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A LITIGATION PRIMER ON KNEE REPLACEMENT SURGERY

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TABLE OF CONTENTS

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INTRODUCTION

"Knee replacement is serious stuff. And, it actually could have made me worse."

— Lee Majors

Billy Joel, Michael Douglas, Lionel Richie, and Jane Fonda may be celebrities with unique talents, but they are no different than the general population when it comes to needing joint replacement surgery.[1] The purpose of this intervention is to replace the damaged parts of a joint with a metal, plastic, or ceramic prosthetic to restore the normal functioning of the area.[2] This surgery is so commonplace that more than two million implant surgeries are performed annually in the United States,[3] and this number continues to expand as the population ages.[4]

This surgery is a viable option for those with advanced joint disease who have failed conservative treatment but continue to suffer significant discomfort that prevents them from engaging in activities of daily living.[5] No timeline exists to dictate when the procedure should be performed. That determination must be premised upon a discussion between the physician and patient that examines "psychological, social, and other issues in addition to pain, disability, and x-ray changes."[6] The factors that must be balanced involve postponing the intervention

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[1] Grace McClure, *17 Famous People Who've Had Joint Replacements*, LINKEDIN (June 21, 2016), https://www.linkedin.com/pulse/17-famous-people-whove-had-joint-replacements-grace-mcclure/.

[2] *See* Jared R.H. Foran, *Total Joint Replacement*, ORTHOINFO (Feb. 2021), https://orthoinfo.aaos.org/en/treatment/total-joint-replacement/.

[3] AM. ACAD. OF ORTHOPAEDIC SURGEONS, *American Joint Replacement Registry Releases 2021 Annual Report, Showing Increase in Number of Hip and Knee Procedures Despite Pause Due to COVID-19*, https://www.aaos.org/aaos-home/newsroom/press-releases/american-joint-replacement-registry-releases-2021-annual-report/ (last visited Apr. 18, 2023) (Hereinafter *2021 Report*); *See* Caryn Etkin & Bryan Springer, *The American Joint Replacement Registry—The First 5 Years,* 3 ARTHROPLASTY TODAY 67, 67-9 (2017), https://www.arthroplastytoday.org/action/showPdf?pii=S2352-3441%2817%2930007-9 (describing the volume of procedures across a number of years).

[4] AM. COLL. OF RHEUMATOLOGY, *Joint Replacement Surgery*, (Feb. 2022), https://www.rheumatology.org/I-Am-A/Patient-Caregiver/Treatments/Joint-Replacement-Surgery#:~:text=Approximately%20790%2C000%20total%20knee%20replacements,in%20any%20area%20of%20medicine.

[5] *Id*.

[6] *See* Barbara Conner-Spady et al., *You'll Know When You're Ready: A Qualitative Study Exploring How Patients Decide When the Time Is Right For Joint Replacement Surgery,* BMC HEALTH SERVICES RESEARCH 1, 2 (2014), http://www.biomedcentral.com/1472-6963/14/454.

thereby increasing the likelihood of a poor surgical outcome versus undergoing the operation too soon causing the prosthetic to wear out.[7]

Knee replacement surgery is the most common form of arthroplasty.[8] However, hip, ankle, elbow, wrist, finger, and shoulders are also routinely replaced.[9] In fact, "joint replacements are one of the most successful procedures in all of medicine."[10]

This article cannot provide an in-depth medical and legal analysis of these various surgeries because of space limitations. Therefore, the commentary will focus on knee replacement surgery since it is the most common arthroplasty. This procedure has resulted in billions of dollars being paid in settlements because of complications, surgical errors, and defective devices.[11] The analysis provided in this primer, however, is not limited to knee replacements. The discussion has application to all forms of joint arthroplasties.

I. THE PROBLEM

It is estimated that one in five people will develop arthritis in the knee with a number of these individuals seeking medical attention because of attendant pain and disability.[12] Various treatment options exit to alleviate the problem, from conservative care to surgery.[13] A total knee replacement ("TKA") or knee arthroplasty is primarily performed to resurface a knee damaged by arthritis which degenerative condition isn't a single ailment.[14] This problem is associated with joint pain or joint disease, with more than 100 kinds of arthritis and associated

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[7] *See id*.

[8] *See generally* AM. ACAD. OF ORTHOPAEDIC SURGEONS, AM. JOINT REPLACEMENT REGISTRY, Annual Report, (James Browne ed.) (2021), https://www.aaos.org/aaos-home/newsroom/press-releases/american-joint-replacement-registry-releases-2021-annual-report/ (providing an encyclopedic catalog of sequences of hip and knee arthroplasty surgeries and results in the United States).

[9] *See* CREAKY JOINTS, *Joint Replacement*, https://creakyjoints.org/education/joint-replacement/#:~:text=Joint%20replacement%20surgeries%20can%20be,restore%20movement%20and%20relieve%20pain (last visited Nov. 16, 2022).

[10] TETON ORTHOPEDICS, *Total Joint Replacement*, https://www.tetonortho.com/total (last visited Nov. 18, 2022).

[11] *See* Terry Turner, *Knee Replacement Lawsuits*, DRUGWATCH.COM (Nov. 4, 2022) (Emily Miller ed.) https://www.drugwatch.com/knee-replacement/lawsuits/.

[12] *See* HSS, *Partial Knee Replacement: A Treatment Option in Unicompartmental Knee Arthritis,* https://www.hss.edu/conditions_partial-knee-replacement.asp (last visited Nov. 11, 2022).

[13] See *id*.

[14] *See* JOHNS HOPKINS MEDICINE, *Knee Replacement Surgery Procedure*, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/knee-replacement-surgery-procedure (last visited Apr. 19, 2023) (Hereinafter *Knee Replacement Surgery Procedure*).

disorders.[15] Arthritis does not discriminate. It affects individuals of all ages, races, and sexes. In fact, it is the primary reason for disability in this country.[16]

Knee arthritis is particularly troublesome because it can interfere with most activities of daily living,[17] such as running, ambulating, or climbing stairs. It results in lost time from work and creates a serious disability for many individuals.[18] The primary arthritic conditions of the knee include osteoarthritis, rheumatoid arthritis, and traumatic arthritis.[19]

Osteoarthritis is a degenerative joint disease that usually affects middle-aged and older adults. It can lead to a breakdown of joint cartilage and contiguous bone.[20] This condition is responsible for 94–97% of TKA surgeries.[21] Risk factors "include bone density, bone morphology, meniscal derangement, sex hormones, and trauma, but the largest risk factors are age and obesity."[22]

Rheumatoid arthritis is a persistent problem that attacks various joints in the body, among them being the knee.[23] The disease is symmetrical in that it disturbs the same joint on both sides of the body.[24] This form of arthritis is an autoimmune disorder that causes inflammation to the knee's synovial membrane and results in an excessive build-up of fluid, leading to discomfort and stiffness.[25]

Traumatic arthritis stems from an injury to the knee that damages the joint's cartilage.[26] For instance, a fracture may harm the surfaces of the joint, resulting in post-traumatic arthritis. Tears of the meniscus and ligaments can also cause insecurity and extra friction on the knee, which with time, may cause arthritis.[27]

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[15] *See* Linda Rath, *What is Arthritis*, ARTHRITIS FOUND (June 9, 2022), https://www.arthritis.org/health-wellness/about-arthritis/understanding-arthritis/what-is-arthritis.
[16] *See id*.
[17] Peter F. Edemekong et al., *Activities of Daily Living*, NAT'L LIBRARY OF MEDICINE (Nov. 19, 2022) https://www.ncbi.nlm.nih.gov/books/NBK470404/#article-17137.s3.
[18] Jared R.H. Foran, *Arthritis of the Knee,* ORTHOINFO (Feb. 2021), https://orthoinfo.aaos.org/en/diseases--conditions/arthritis-of-the-knee/#:~:text=Rheumatoid%20arthritis%20is%20a%20chronic,knee%20joint%20begins%20to%20swell.
[19] *Id*.
[20] *See id*.
[21] Andrew Carr et al., *Knee Replacement*, 379 THE LANCET 1331 (Apr. 7, 2012) https://pubmed.ncbi.nlm.nih.gov/22398175/.
[22] *See id*.
[23] *See Rath, supra* note 15.
[24] *See id*.
[25] *See id*.
[26] *Id*.
[27] PENN MEDICINE, *Meniscus Teras: Why You Should Not Let Them Go Untreated*, https://www.pennmedicine.org/updates/blogs/musculoskeletal-and-rheumatology/2018/september/meniscus-tears-why-you-should-not-let-them-go-untreated#:~:text=If%20not%20treated%2C%20part%20of,to%20complications%2C%20such%20as%20arthritis. (last visited Apr. 18, 2023).

Less frequent causes of a TKA include hemophilia, gout, unusual bone growth, and interruption of the blood supply to the knee, causing the bone to die.[28]

As "baby boomers" age, there has been a dramatic increase in the diagnosis and treatment of progressive arthritic changes as well as increased requests for better mobility and quality of life.[29] It is no surprise, that the number of TKAs has increased, resulting in joint replacements becoming the most frequent elective surgical procedure.[30] In some instances, patients will outlast their knee replacement and need a joint revision with significant costs and resource utilization.[31] Since a knee replacement is generally expected to last fifteen years,[32] a number of these individuals will believe someone was at fault if their implant fails prematurely and seek legal advice about a possible claim.

II. ANATOMY OF THE KNEE

Understanding the knee's anatomy is necessary to appreciate how a knee replacement is performed**.** The knee is recognized as one of the most complex joints in the body.[33] It connects the bones of the upper and lower leg to allow people to engage in activities of daily living.[34] It is a hinged joint whose anatomical construction makes it susceptible to injury. The knee is designed so it can move up and down while it can also rotate sideways.[35] This four-way movement offers very little stability to provide maximum flexibility.[36]

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[28] *See* NHS, *Overview – Knee Replacement*, https://www.nhs.uk/conditions/knee-replacement/ (last visited Jan. 27, 2023).

[29] Suzanne G. Leveille et al., *Trends in Obesity and Arthritis Among Baby Boomers and Their Predecessors, 1971-2002*, AM. J. PUBLIC HEALTH (Sept. 2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1449405/.

[30] *See* Hilal Maradit Kremers, et. al., *Prevalence of Total Hip and Knee Replacement in the United States,* 97(17) THE J. OF BONE AND JOINT SURGERY, AM. VOLUME 1386, 1386 (2015).

[31] *See id*. at 1387.

[32] *See* MAYO CLINIC, https://www.mayoclinic.org/tests-procedures/knee-replacement/about/pac-20385276#:~:text=For%20most%20people%2C%20knee%20replacement,last%20more%20than%2015%20years (last visited Jan. 27, 2023).

[33] *See* Samuel D. Hodge, Jr., and Jack E. Hubbard, *Clinical Anatomy for Lawyers*, AM. BAR ASSOC., 2012 1, 174.

[34] *See* NAT'L LIBR. OF MED. *How Does the Knee Work?,* https://www.ncbi.nlm.nih.gov/books/NBK561512/#:~:text=The%20muscles%20and%20tendons%20allow%20the%20knee%20to%20move&text=The%20quadriceps%20femoris%20on%20the,possible%20to%20bend%20the%20knee (last visited Apr. 19, 2023).

[35] Samuel D. Hodge, Jr., *A Litigation Primer on the Knee*, 15 No. 4 PRAC. LITIGATOR 7*, at *8 (2004).

[36] *Id*.

A. Bones

The knee consists of multiple structures: bones, cartilage, muscles, tendons, and ligaments.[37] A total of four bones are involved in the joint's construction: the femur, tibia, fibula, and patella. The femur is in the thigh and is the largest bone in the body.[38] Its average adult length reaches eighteen inches long.[39] It plays a vital role in how people stand, move, and keep their balance.[40] While the upper part of this bone connects to the hip, its lower aspect forms the top of the knee joint and includes two rounded surfaces; the condyles.[41] These twin structures are encased in articular cartilage and serve as shock absorbers for the knee.[42] The medial condyle is situated on the inside part of the knee, and the lateral condyle is positioned on the outside part of the joint.[43]

The second bone is the tibia or shinbone, the bigger of the two bones in the lower aspect of the limb. It forms the bottom part of the knee joint and can be found on the inside part of the lower leg.[44] Functionally, this bone supports most of the body's weight.[45] The top portion of the tibia contains two flat surfaces; the tibial plateau which communicates with the corresponding bottom surfaces of the femur.[46]

The fibula is the smaller bone in the lower leg and sits adjacent to the tibia. It is found on the lateral side of the limb.[47] Muscle attachments govern its shape. Its top aspect resembles a triangle, and the lower part is irregularly

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[37] *See* NAT'L LIBR. OF MED.*, supra* note 34 at *1.

[38] CLEVELAND CLINIC, *Femur*, https://my.clevelandclinic.org/health/body/22503-femur (last visited (Apr. 18, 2023).

[39] *Id*.

[40] *See id*.

[41] *See id*.

[42] *See* Robert LaPrade, *Femoral Condyles – Anatomy*, ROBERT LAPRADE MD, PHD, https://drrobertlaprademd.com/femoral-condyle-articular-cartilage-injury-oats-treatment-minneapolis-st-paul-edin -eaganmn/#:~:text=Femoral%20Condyles%20%E2%80%93%20Anatomy%3A,shock%20absorber%20for%20the%20knee (last visited Jan. 27, 2023).

[43] *See id*.

[44] *Hodge*, *supra* note 35 at *8.

[45] Jason A. Lowe, *Tibia (Shinbone) Shaft Fractures,* ORTHOINFO, https://orthoinfo.aaos.org/en/diseases--conditions/tibia-shinbone-shaft-fractures (last visited Jan. 27, 2023).

[46] BRITANNICA, *Tibia*, https://www.britannica.com/science/tibia (last visited Nov. 10, 2022).

[47] *Hodge*, *supra* note 35 at *8.

designed.[48] This bone has no weight-bearing function, and its primary purpose is to join with the tibia to offer stability to the ankle.[49]

The last bone is the patella or kneecap.[50] This structure is considered a sesamoid bone and is several inches in diameter.[51] During movement of the leg, it will slide up and down over the bottom aspect of the femur or femoral grove.[52] The patella protects the knee and offers leverage to the thigh muscles or quadriceps.[53]

B. Articular Cartilage

Dense and smooth articular cartilage[54] covers the ends of the bones. This slippery element assists in dissipating shock and helps the bones during movement by providing a smooth surface.[55] Fluid created within the synovial joint lubricates this tissue, permitting the bones to slide over one another, such as when the knee bends.[56]

It helps disperse the load between the knee's cartilage surfaces.[57] These C-shaped cushions separate the femur and tibia. They also keep the femur and tibia from rubbing against each other.[58] The menisci are named according to their anatomic orientation.[59] The cushion on the inside of the knee is the medial meniscus and attaches to the medial collateral ligament.[60] The lateral or outer meniscus is the larger of the two structures.[61] Because it is more mobile, the lateral meniscus is less often injured.[62] Together, the menisci cover about 2/3 of the tibial surface and are

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[48] *See* Marco Gupton, Akul Munjal, & Michael Kang, *Anatomy, Bony Pelvis and Lower Limb, Fibula*, NAT'L LIBR. OF MED., NAT'L INST.OF HEALTH, May 29, 2022, https://www.ncbi.nlm.nih.gov/books/NBK470591/.
[49] *Id*.
[50] James Baldwin & Ken House, *Anatomic Dimensions of the Patella Measured During Total Knee Arthroplasty*, J. OF ARTHROPLASTY (2005).
[51] *Id*.
[52] *Hodge*, *supra* note 35 at *8.
[53] *Hodge & Hubbard*, *supra* note 33 at 175.
[54] Articular refers to "having to do with joints." *See* YALE MED., *Cartilage Injury and Repairs*, https://www.yalemedicine.org/conditions/cartilage-injury-and-repair#:~:text=The%20most%20common%20type%20of,cartilage%20known%20as%20articular%20cartilage (last visited Nov. 10, 2022).
[55] *Hodge*, *supra* note 35 at *8.
[56] *YALE MED., supra* note 50.
[57] *Id*.
[58] *Hodge*, *supra* note 35 at *9.
[59] *Id*.
[60] James K. Bryceland et al., *Cartilage*, SAGE J. (2007).
[61] *Id*.
[62] *See id*.

thicker on the outside and thinner on the inside areas.[63] These structures fill the space between the bones of the knee and cushion the femur "so it doesn't slide off or rub against the tibia."[64] The outer part of the meniscus is supplied with little blood so it can't repair itself if damaged.[65]

C. Ligaments

The knee is held tighter by four bands of cord-like tissue, the cruciate and collateral ligaments.[66] The cruciate ligaments crisscross in the center of the joint and are essential to the main movement of the knee; flexion and extension.[67] The anterior cruciate ligament (ACL) is the most well-known of these ligaments and connects the anterior aspect of the tibia to the posterior portion of the femur.[68] Its task is to stop the tibia from moving forward in front of the femur and provides the knee with rotational stability.[69] The average length of the ACL is between 26 mm to 38 mm.[70]

The posterior cruciate ligament (PCL) is a short and thick structure that starts at the back of the tibia and attaches to the femur.[71] Its job is to stop the abnormal backward movement or hyperflexion of the tibia.[72] The PCL is about the size of a person's finger and is the strongest ligament in the joint.[73] This ligament is less frequently injured because of its strength.[74]

The two remaining ligaments are the collateral ligaments. Their job is to stabilize the knee when it moves sideways.[75] The ligament located on the

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[63] AID MY MENISCUS, *Knee and Meniscus Anatomy*, https://aidmymeniscus.com/meniscus-injuries/information.php (last visited Nov. 10, 2022).
[64] *See id.*
[65] *See* Alice Fox, et. Al, *The Basic Science of Human Knee Menisci: Structure, Composition, and Function,* 4 SPORTS HEALTH 340 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3435920/.
[66] ORTHOINFO, *Anterior Cruciate Ligament (ACL) Injuries*, https://orthoinfo.aaos.org/en/diseases--conditions/anterior-cruciate-ligament-acl-injuries/ (last visited Apr. 18, 2023).
[67] *Hodge and Hubbard*, *supra* note 33 at 175.
[68] *Id*.
[69] *See* ORTHOINFO, *Anterior Cruciate Ligament (ACL) Injuries*, https://orthoinfo.aaos.org/en/diseases--conditions/anterior-cruciate-ligament-acl-injuries/ (last visited Nov. 10, 2022).
[70] *See* Stephanie G. Cone et al., *Size and Shape of the Human Anterior Cruciate Ligament and the Impact of Sex and Skeletal Growth: A Systematic Review,* 7(6) JBJS REV. 1 (2019).
[71] ORTHOINFO, *Posterior Cruciate Ligament (PCL) Injuries*, https://orthoinfo.aaos.org/en/diseases--conditions/posterior-cruciate-ligament-injuries/ (last visited Apr. 18, 2023).
[72] *Hodge & Hubbard*, *supra* note 33 at 175.
[73] *See* ORTHOINFO, Posterior Cruciate Ligament (PCL) Injuries, https://orthoinfo.aaos.org/en/diseases--conditions/posterior-cruciate-ligament-injuries/ (last visited Nov. 10, 2022).
[74] *See id*.
[75] *See Hodge & Hubbard*, *supra* note 33 at 175.

outside of the knee is the lateral collateral ligament. It attaches to the fibula and femur to stabilize that portion of the joint. The opposite ligament is the medial collateral ligament, and this structure connects to the inside of the femur and tibia, thereby offering stability to the inner part of the knee.[76]

D. Muscles

The knee contains several muscles that allow for limb movement in various directions. The quadriceps, a group of four muscles in the front of the thigh, is the largest in the leg and permits knee extension. It plays a critical role in the ability to walk by allowing the leg to move forward.[77] The individual muscles in this group are the rectus femoris, the vastus lateralis, the vastus intermedius, and the vastus medialis.[78] Collectively, these muscles make up the bulk of the thigh and produce one of the strongest muscle arrangements in the body.[79] They also assist in stabilizing the knee by keeping the patella inside a groove in the femur.[80]

The quadriceps work opposite to another set of muscles in the leg, the hamstring, located in the back of the thigh. The hamstring runs from the hip to just below the knee.[81] Its function is to permit the lower aspect of the leg to flex at the knee.[82] The hamstring consists of the biceps femoris, semitendinosus, and semimembranosus muscles.[83] They assist a person with bending and extending the knee, and with hip rotation.[84]

E. Tendons of the Knee

A tendon forms at the end of a muscle and connects the structure to bone on the opposite side of a joint. The knee has multiple tendons, but the largest is the patellar tendon.[85] It originates at the quadriceps and stretches downward, attaching

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[76] *See id*.
[77] *See id*. at 176.
[78] Louise Morales-Brown, *What to Know About the Quadriceps Muscles,* MED. NEWS TODAY, (Jan. 27, 2022) https://www.medicalnewstoday.com/articles/quadriceps-muscles.
[79] *See id*.
[80] *See id*.
[81] *Hodge & Hubbard*, *supra* note 33 at 176.
[82] *Id*.
[83] *Id*.
[84] *See* CLEVELAND CLINIC, *Hamstring Muscles*, https://my.clevelandclinic.org/health/body/21904-hamstring-muscles (last visited Nov. 10, 2022).
[85] Zinovy Meyler, *Knee Anatomy*, ARTHRITIS-HEALTH (Nov. 21, 2018), https://www.arthritis-health.com/types/joint-anatomy/knee-anatomy.

the patella to the front of the tibia.[86] A contraction of this muscles will pull the patellar tendon causing the leg to straighten.[87] Other tendons include the quadriceps and hamstring tendons.[88]

F. Knee Bursa

Bursae are small sacs that are located around the knee joint and are filled with synovial fluid.[89] Their task is to reduce friction created by the movement of muscles and tendons, thereby allowing the joint to move smoothly.[90] The knee has roughly fourteen sacs; the prepatellar knee bursa is the most well-known.[91] This bursa sits in front of the patella. The infrapatellar knee bursae are two additional sacs situated just below the kneecap.[92]

III. KNEE REPLACEMENT SURGERY

A. Non-Surgical Options

Surgical intervention is a "last resort" for most people.[93] A variety of non-surgical options exist to alleviate the discomfort of a failing knee. For younger adults or those who have a medical issue that could complicate surgery, the best option is to defer surgical intervention as long as possible.[94] Conservative care should include lifestyle modifications such as physical therapy, weight loss**,** non-steroidal anti-inflammatory drug use, steroid medication, braces or splints, joint supplements like glucosamine and chondroitin, and stretching before activity.[95]

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[86] *Id*.
[87] *Id*.
[88] Adam Pourcho, *Soft Tissues of the Knee Joint*, SPORTS-HEALTH (Nov. 11, 2015), https://www.sports-health.com/sports-injuries/knee-injuries/soft-tissue-knee-joint.
[89] Chole Wilson, *Knee Bursa*, KNEE PAIN EXPLAINED, https://www.knee-pain-explained.com/KneeBursa.html (last visited Nov. 13, 2022).
[90] *See id*.
[91] *See id*.
[92] *Id*.
[93] *See When Should You Get A Knee Replacement*, UNIV. OF UTAH HEALTH, https://healthcare.utah.edu/orthopaedics/specialties/joint-replacement/when-should-you-get-a-knee-replacement.php#:~:text=%2F%201%3A42-,How%20Long%20Does%20It%20Take%20to%20Recover%20From%20a%20Knee,your%20knee%20regains%20full%20function (last visited Nov. 11, 2022).
[94] *See* U.S. OLYMPIC AND PARALYMPIC TRAINING CTR., *Non-Surgical Options Before Considering Joint Replacement*, https://ccoe.us/joint-replacement/non-surgical-options-before-considering-joint-replacement/ (last visited Apr. 19, 2023).
[95] *See id*.

B. Surgery

If non-surgical treatments fail and walking supports are no longer helpful, a person may be a candidate for knee replacement surgery.[96] This intervention aims to alleviate discomfort, improve the quality of life, and preserve or increase knee performance.[97] Anyone is a candidate for this surgery unless they are a child, whose bones are still growing.[98] A recommendation for surgery is based on a person's pain and disability and most patients who have knee replacements are between 50 to 80.[99]

Total knee arthroplasty had its origins in the early 1860s when a German doctor surgically implanted a primitive hinged joint made of iron.[100] The first knee replacement was performed in 1968 and it has come a long way since then.[101] The procedure gained widespread favor in the 1970s and 1980s.[102] The initial prosthetics were created by surgical innovators in partnership with industry.[103] However, it is a misnomer to say the knee is being replaced.[104] Simply put, the eroded ends of the surfaces of the tibia and femur are cut off and replaced with "metal and plastic parts (a prothesis) which have been modified to fit."[105] The surgeon will perform either a total or partial replacement based upon how much deterioration the knee has sustained.[106] Currently, more than 19 firms in the United States sell total knee implants of three different kinds: cruciate-preserving, cruciate-substituting, and TC-III.[107] Six businesses are designing mobile-bearing knees, and future innovations include robotically guided surgery, augmented kinematics, and wear-resistant bearing surfaces with improved fixation that promise an unfailing

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[96] *See* ORTHOINFO, *Total Knee Replacement*, AM. ACAD. OF ORTHOPAEDIC SURGEONS, https://orthoinfo.aaos.org/en/treatment/total-knee-replacement (last visited Nov. 11, 2022).
[97] Gregory M. Martin, *Patient education: Total knee replacement (Beyond the Basics),* UPTODATE (May 17, 2022), https://www.uptodate.com/contents/total-knee-replacement-beyond-the-basics#:~:text=The%20most%20common%20reason%20for,maintain%20or%20improve%20knee%20function.
[98] *But see ORTHOINFO*, *supra* note 96.
[99] *Id*.
[100] *See The History of Knee Replacement and Current Advances in Total Knee Replacement,* INTEGRATED ORTHOPEDICS, https://integratedorthopedicsaz.com/articles/the-history-of-knee-replacement-and-current-advances-in-total-knee-replacement/ (last visited Nov. 14, 2022).
[101] *ORTHOINFO*, *supra* note 96.
[102] *See Carr*, *supra* note 21.
[103] *See id*.
[104] *See id*. at *3.
[105] *See* NHS, *How Is It Performed*, https://www.nhs.uk/conditions/knee-replacement/what-happens/ (last visited Nov. 11, 2022) (Hereinafter *How Is It Performed*).
[106] *See id*.
[107] *See* Chitranjan S Ranawat, *History of Total Knee Replacement,* 11(4) J. SOUTH ORTHOP. ASSOC. 218-26 (2002).

evolution for the device.[108] Surgeons are even doing minimally-invasive quadriceps-sparing TKAs that permit the physician to implant the traditional knee replacement through a much smaller incision.[109] This procedure circumvents injury to the quadriceps muscle which is the most important muscle group around the knee.[110]

1. Total Knee Replacement

A total knee replacement has become a standard procedure that requires both surfaces of the femur and tibia to be replaced.[111] However, not everyone is a candidate, and a successful outcome depends on proper patient selection.[112] The major determining factors for TKA are end-stage knee arthritis and dogged severe discomfort.[113] These individuals receive little help from arthroscopic surgery, and osteotomy around the knee is generally limited to those younger than 55 years.[114] Most patients have "end-stage radiographic disease," and the person's symptoms should dictate the surgery.[115] These determining factors include a history of continuing pain, at night or with weight bearing, and the complaints should not abate despite a 6-month course of conservative care.[116] While age or being overweight no longer disqualify a person, patients must appreciate the advantages and risks of the procedure.[117]

This surgery requires several steps. Initially, the doctor will make a long incision in the front of the knee to expose the patella.[118] The kneecap is then retracted to reveal the joint behind it.[119] The surfaces of the cartilage at the ends of the femur and tibia are cut away "along with a small amount of underlying bone."[120] The ends of the bones are carefully measured, and cuts in the bones are made to accommodate the shape of the prosthetic that will reestablish the

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[108] *Id*.
[109] *Id*.
[110] *See* Seth S. Leopold, M.D., *Minimally-Invasive Surgery (MIS) Quadriceps-Sparing Total Knee Replacement,* UW MEDICINE, https://orthop.washington.edu/patient-care/articles/knee/minimally-invasive-surgery-mis-quadriceps-sparing-total-knee-replacement (last visited Nov. 14, 2022).
[111] *See How Is It Performed, supra* note 105.
[112] Kevin Bocgic, *Undergoing Total Knee Replacement for Knee Arthritis*, ARTHRITIS-HEALTH (Sept. 6, 2018), https://www.arthritis-health.com/surgery/knee-surgery/undergoing-total-knee-replacement-knee-arthritis.
[113] *See Carr*, *supra* note 21.
[114] *See id*.
[115] *See id*.
[116] *See id*.
[117] *See id*.
[118] *How Is It Performed, supra* note 105.
[119] *Id*.
[120] *ORTHOINFO*, *supra* note 96 at *3.

shape of the joint.[121] A sample prosthetic is placed in the area to see if it fits. The knee is then moved back and forth to ascertain if it works correctly. Following the necessary adjustments, the ends of the bones are cleaned, and the shaved surfaces are fitted with the final prosthetic.[122] A curved piece of metal in the shape of the femoral condyle is inserted at the top and the tibia plateau on the bottom is replaced with a flat piece of metal.[123]

Many different types of prosthetics can be implanted. While most physicians use a metal-on-plastic implant, they can also be constructed of ceramic on plastic, ceramic on ceramic, and metal on metal.[124] More than 150 variations of these devices exist based on the recipient's size and activity level.[125] However, the critical factor in selection is whether the replacement will cover the entire joint or only a portion.[126]

Most implants are affixed to the patient's bone with a quick-drying cement mixed in the operating room.[127] A second method uses an implant that has a textured surface, known as a press-fit implant, designed to stimulate bone growth.[128] This procedure allows the patient's bone to incorporate into the implant to form a solid fusion.[129]

The back of the patella is then removed, and a plastic spacer may be inserted between the pieces of metal.[130] This spacer acts like a meniscus to provide a smooth gliding surface.[131] Once the physician ascertains that the knee is mechanically sound and working properly, the wound is stitched, and the area is bandaged to provide a sterile environment.[132] The procedure generally takes between one to three hours.[133]

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[121] *See How Is It Performed*, *supra* note 105.
[122] *See id*.
[123] *See id*.
[124] *See* HARV. HEALTH PUBL'G, *4 Types of Knee Implants*, https://www.health.harvard.edu/pain/4-types-of-knee-implants (last visited Apr. 18, 2023).
[125] Samuel Greengard, *Guide to Knee Replacement Implants and Their Manufacturers*, HEALTHLINE (Apr. 9, 2018), https://www.healthline.com/health/total-knee-replacement-surgery/common-questions (Hereinafter *Greengard*).
[126] *See* NAT'L LIBR. OF MED., Osteoarthritis *of the Knee: What Different Types Of Knee Implants Are There?,* https://www.ncbi.nlm.nih.gov/books/NBK544988/ (last visited Apr. 18, 2023).
[127] *See* R. Michael Meneghini, *Cemented vs. Cementless Knee Replacement*, IND. JOINT REPLACEMENT INST., https://www.meneghinimd.com/specialties/cemented-vs-cementless-knee-replacement (last visited Nov. 13, 2022).
[128] *See id*.
[129] *See NAT'L LIBR. OF MED.*, *supra* note 126.
[130] *Id*.
[131] *See id*.
[132] *See How Is It Performed*, *supra* note 105.
[133] *See id*.

2. Partial Knee Replacement

Unicompartmental osteoarthritis occurs when only a portion of the knee is affected by advanced degenerative changes.[134] At the same time, the remaining aspect of the joint is healthy.[135] This condition permits a surgeon to perform a less extensive revision to remedy the problem; a partial knee replacement. This process involves either resurfacing the medial or lateral component of the joint with the insertion of a prosthetic limited to the affected area.[136] Traditionally, this intervention was restricted to less active older adults.[137] This thought process has changed, and a partial knee replacement is frequently performed in younger patients since their recovery is faster with less discomfort.[138] It is estimated that 5% to 6% of people with arthritic knees qualify for this procedure.[139]

There are several advantages to this surgery.[140] A partial knee replacement results in a better range of motion and knee function since it "preserves healthy tissue and bone in the knee."[141] The procedure only requires a 3-to-4-inch incision in the front of the knee, and there is no disruption of the quadriceps tendon.[142] This results in less trauma and blood loss.[143] Since the knee ligaments are maintained, the joint feels more normal, particularly with strenuous activities.[144] However, the benefits of this surgery must be offset against the high rate of revision surgery mandated to remove, or replace segments of the partial knee replacement.[145]

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[134] *HSS*, *supra* note 12.
[135] *Id*.
[136] *See id*.
[137] CLEVELAND CLINIC, *Partial Knee Replacement: Is It For You?*, https://my.clevelandclinic.org/health/treatments/14599--partial-knee-replacement (last visited Nov. 11, 2022).
[138] *Id*.
[139] *See id*.
[140] *Id*.
[141] *See id*.
[142] *See* Moby Parsons, *Partial Knee Replacement: Who is a Candidate and What are the Advantages and Disadvantages?,* ATL. COAST SURGICAL SUITES, LLC*, https://atlanticcoastss.com/partial-knee-replacement-who-is-a-candidate-and-what-are-the-advantages-and-disadvantages/* (last visited Nov. 11, 2022).
[143] *See* BEACON ORTHOPEDIC & SPORTS MED., *The Benefits of Partial Knee Replacements*, https://www.beaconortho.com/blog/benefits-partial-knee-replacements/ (last visited Nov. 11, 2022).
[144] *See id*.
[145] *See HSS*, *supra* note 12.

3. Revision Surgery

Knee replacement surgery is very successful, but it has a shelf-life. Most implants last 15 to 20 years.[146] Statistically, 3.9% of patients require revision surgery within ten years, and 10.3% need additional surgery by their twentieth anniversary.[147] However, as the number of surgeries has increased, knee revisions multiple as well.[148] It is estimated that 572,000 knee revisions will be performed annually by 2030.[149] The longevity of a TKS is dependent on a variety of influences including the skill of the surgeon and technique employed, the frequency the procedure is performed at the medical facility, and patient factors such as age, weight, and activity level.[150]

A knee replacement may fail for various reasons. The prosthetic must be affixed to the bone for it to work correctly.[151] This is usually achieved by cementing the implant onto the bone. While the device may be firmly secured during surgery, it may loosen over time.[152] The reason for this failure may not always be appreciated, but "high impact activities, excessive body weight and wear of the polyethylene component may all act as contributing factors."[153] Over time, the joint surfaces will also deteriorate from the friction created by rubbing against each other. This activity allows small elements to collect around the joint.[154] Known as aseptic loosening, these particles disrupt the bond between the implant and the bone.[155]

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[146] *See* PERSONALIZED ORTHOPEDICS OF THE PALM BEACHES, *How Long Will A Knee Replacement Implant Last?,* https://www.popb.md/2022/02/11/how-long-will-a-knee-replacement-implant-last/ (last visited Apr. 19, 2023) (Hereinafter *PALM BEACHES*).

[147] Robert Shmerling, *How Long Will My Hip or Knee Replacement Last*, HARV. HEALTH BLOG (Mar. 29, 2021) https://www.health.harvard.edu/blog/how-long-will-my-hip-or-knee-replacement-last-2018071914272.

[148] *See* Zachary Lum et al., *Why Total Knees Fail-A Modern Perspective Review,* 9(4) WORLD J. ORTHOPEDICS 60, 62 (2018).

[149] *See* Michael Geary et al., *Why Do Revision Total Knee Arthroplasties Fail? A Single-Center Review of 1632 Revision Total Knees Comparing Historic and Modern Cohorts,* 35 J. OF ARTHROPLASTY, 2938-2943 (2020).

[150] *See Shmerling*, *supra* note 147.

[151] *PALM* BEACHES, *supra* note 146.

[152] *Id*.

[153] Amar Ranawat, *Revision Total Knee Replacement: Frequently Asked Questions,* HHS, (Aug. 27, 2020), https://www.hss.edu/conditions_revision-total-knee-replacement-faqs.asp#:~:text=to%20revision%20surgery%3F-,What%20causes%20a%20knee%20replacement%20implant%20to%20fail%3F,%2C%20leg%20fractures%2C%20or%20stiffness (Hereinafter *Revision Total Knee Replacement: Frequently Asked Questions)*.

[154] *Id*.

[155] *See id*.

Infections are one of the most serious complications of a knee replacement and the primary cause of failures involving prosthetics.[156] It extends the hospital stay by two to three weeks and doubles the need to be hospitalized with the frequent outcome requiring one or more surgeries.[157] The infection rate can be as high as 3%. Various influence account for this development.[158] Infections occur because harmful bacteria contaminate the surgical site or body.[159] Bacteria are routinely present in people but are neutralized by the immune system. Because the prosthetics used in a TKA are made of metal or plastic, they present a challenge for the immune system's ability to attack these microorganisms.[160] Once the bacteria invade the implant, they can increase in number and trigger an infection.[161]

The symptoms and severity will depend on whether the infection is superficial or more pervasive.[162] A superficial infection occurs at the surgical site. In contrast, a deep knee infection develops around the prosthetic.[163] A superficial infection typically surfaces shortly after surgery. While it is easy to remedy, the infection can become much more sinister if not treated adequately.[164] Treatment includes surgery to cleanse the area and at least a six-week course of antibiotics tailored to the specific pathogen.[165] On the other hand, a deep infection is problematic. It can develop weeks, months, or even years after the operation. Most infections occur, however, within the first twenty-four months of surgery.[166] Unfortunately, this type of complication can result in additional surgery to remove the infected prosthetic.[167]

Counsel investigating a knee infection claim should ascertain if the surgeon investigated the patient's risk factors for developing a complication during the preoperative consultation, such a conversation should always be a focal point of the

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[156] S. Marmor & Y. Kerroumi, *Patient Specific Risk Factors for Infection in Arthroplasty Procedure* 102 ORTHOP. TRAUMATOL: SURG. AND RES. 113-19 (Feb. 2016).
[157] *Id*.
[158] Junren Lu et al., *Infection After Total Knee Arthroplasty And Its Gold Standard Surgical Treatment: Spacers Used In Two-Stage Revision Arthroplasty,* 6 INTRACTABLE RARE DIS. RES. 256 (Nov. 2017).
[159] ORTHOINFO, *Joint Replacement Infection,* https://orthoinfo.aaos.org/en/diseases--conditions/joint-replacement-infection/ (last visited Nov. 12, 2022).
[160] *See id*.
[161] *See id*.
[162] *See Lu*, *supra* note 158.
[163] *See id*.
[164] *See* Timothy Gossett, *What You Should Know About Infections After a Knee Replacement*, HEALTHLINE, April 9, 2020, https://www.healthline.com/health/knee-replacement-infection.
[165] *See* Jonathan Cluett, *Infection After Knee Replacement Surgery*, VERYWELL (Oct. 10, 2022), https://www.verywellhealth.com/infection-after-knee-replacement-2549619.
[166] *See Gosset*, *supra* note 164.
[167] *See id*.

patient's initial meeting since it influences the treatment decision.[168] It is also standard practice for the physician to order preoperative tests to discover comorbidities or other ongoing treatments that may increase the chances of an infection.[169] Eighty percent of surgical candidates have modifiable risk factors such as obesity, smoking, alcoholism, anemia, malnutrition, rheumatoid arthritis, and diabetes.[170] These risks can be controlled, so it is important to take prophylactic measure to minimize them as much as feasible.[171]

Revision surgery is more complex and takes longer than the initial replacement. It involves several steps.[172] The first measure requires the removal of the original prosthetic. The physician will attempt to follow the original incision line.[173] However, the new opening may be more extensive than the original scar to accommodate the removal of the old device.[174] Bone grafts may be employed to fill any holes that have occurred due to deteriorating bone.[175] In that case, new bone must be harvested from the patient's body, or a bone bank will be employed.[176] Occasional, the bone may need to be secured with metal wedges, plates, or screws.[177] The next step requires the insertion of specially crafted revision knee implants.[178] Drains may be used for a few days to retard the swelling of the joint. Attempts to improve wound healing are made by applying negative pressure incisional dressings. This remedial measure has been shown to reduce complications in high-risk patients.[179] Revision surgery does not enjoy the same success rate as the initial TKA and is subject to more significant complications. The replacement device also does not last as long as the original prosthetic.[180]

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[168] *See Marmor & Kerroumi*, *supra* note 156.
[169] *See id*. at *3.
[170] See *id*.
[171] *See id*.
[172] *See Revision Total Knee Replacement: Frequently Asked Questions*, *supra* note 153.
[173] *Id*.
[174] *See* ORTHOINFO, *Joint Replacement Infection*, https://orthoinfo.aaos.org/en/diseases--conditions/joint-replacement-infection/ (last visited Nov. 12, 2022).
[175] *See id*.
[176] *See Revision Total Knee Replacement: Frequently Asked Questions*, *supra* note 153.
[177] *See id*.
[178] *See id*.
[179] *See id*.
[180] *See* Nicklya Harris-Ray, *What to Know About Knee Replacement Revision Surgery,* WEBMD (Nov. 22, 2021), https://www.webmd.com/pain-management/knee-pain/what-to-know-about-knee-replacement-revision-surgery.

IV. LEGAL CONSIDERATIONS

A. Lawsuits

Research, planning, and care in the design of a knee prosthetic does not prevent a defect or recall.[181] Implants are amazingly sophisticated, but issues still arise. A defect in the product or negligence on the part of the physician can have significant repercussions.[182] For instance, Sulzer Medica was required to pay $1 billion to resolve 4,000 hip and knee implant claims.[183] Other manufacturers like DePuy, Stryker, Zimmer, and Exactech are facing thousands of knee replacement lawsuits resulting from various alleged defects in their products.[184] Many of these matters maintain the manufacturers did not adequately warn patients about the risks presented by their devices.[185] It is further asserted the prosthetic loosened, causing instability, and requiring revision surgery.[186]

A knee replacement is also subject to recall. This action occurs when an implant needs corrective action or is being withdrawn from use.[187] A correction focuses on a problem with the unit where "it was sold or used."[188] A removal withdraws the implant from sale to examine an issue that has developed.[189] This remedial action can be voluntarily initiated by the manufacturer or mandated by the government.[190] According to the Food and Drug Administration, almost 1,300 knee prosthetic products were recalled between 2003 and 2019.[191] These notices were primarily based on device design and process control. "Tibial components accounted for 35.33% of [the recalled devices], polyethylene implants for 38.67%, and femoral components for 15%."[192]

Studies reveal that the cost of patient care and litigation can be driven by the efforts of the medical healthcare industry to sell products, devices, drugs, and

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[181] *See Greengard*, *supra* note 125.
[182] *See id*.
[183] *See id*
[184] *See* SEEGER WEISS, LLP, *Knee Replacement Lawsuit*, https://www.seegerweiss.com/product-liability/knee-replacement-lawsuit/ (last visited Nov. 13, 2022).
[185] *See* Katy Moncivais, *Understanding Knee Replacement Lawsuits*, *Exactech, Stryker and More*, CONSUMER SAFETY, https://www.consumersafety.org/medical-device-lawsuits/knee-replacement/.
[186] *See Turner*, *supra* note 11.
[187] *See* DRUG DANGERS, *Knee Replacement Recalls*, https://www.drugdangers.com/knee-replacement/recalls/ (last visited Nov. 23, 2022).
[188] *Id*.
[189] *See id*.
[190] *See id*.
[191] *See Turner*, *supr*a note 11.
[192] Carl Pellerin et al., *Recall Rates of Total Knee Arthroplasty Devices Are Dependent on the FDA Approval Process,* CUREUS (Aug. 14, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7489788/.

pharmaceuticals.[193] Cases involving product liability law in the context of medical devices are illustrative of the difficulty of holding medical device manufacturers accountable for defective products.[194]

Also, the Federal Food & Drug Administration cannot be counted upon to protect the patient. As stated in the amicus curiae brief in *Melissa Ebert v. C.R. Bard, Inc.,* "[s]trict reliance on the FDA to police manufacturers and safeguard the public is likely to jeopardize the consumer/patient given the limited resources of the FDA, its sometimes revolving-door environment, and the political pressures brought to bear by the medical device industry."[195]

B. Multidistrict Litigation

About 20% of TKA patients are unhappy with their surgical outcomes.[196] Certain demographic traits have been linked to this dissatisfaction. These include being a woman, a younger or older patient, having rheumatoid arthritis, pain that has worsened following the intervention, and a pessimistic personality.[197] This dissatisfaction often leads to litigation, and the most frequent complaints are complications due to a prosthetic failure, such as a device loosening or a defect involving the product.[198] Patients also harbor a belief that when something goes wrong with a knee unit, the surgeon committed malpractice.[199] However, the problem may have arisen during the manufacturing process. These types of lawsuits are often premised on products liability theories that: (1) the manufacturer marketed the implant as safe when it was faulty; (2) the implant was poorly designed; or (3) the manufacturer failed to adequately warn the user of the risks or potential harm

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[193] *E.g.*, Ray Moynihanet al., *Selling Sickness: The Pharmaceutical Industry and Disease Mongering,* BMJ. 2002 Apr 13; 324(7342): 886–891.

[194] Correspondence from Clifford Rieders, Esquire, senior partner, Rieders, Travis, Dohrmann, Mowrey, Humphrey and Waters Law Firm, on December 11, 2022. Mr. Rieders is a plaintiff's personal injury lawyer who has handled products liability cases involving medical products and malpractice claims against health care providers. These statements are his thoughts and writings based upon his experience.

[195] *Melissa Ebert v. C.R. Bard, Inc.,* Docket No. 26EAP 2021, Brief of Amici Curiae Gross, et al., on Petition for Certification of Question of Law in the United States Court of Appeals for the Third Circuit, p. 7.

[196] *See* Rajitha Gunaratne et al., *Patient Dissatisfaction Following Total Knee Arthroplasty: A Systematic Review of the Literature,* 32 J. OF ARTHROPLASTY 3854 (2017).

[197] *See* C. Scott et al., *Predicting Dissatisfaction Following Total Knee Replacement,* 92-B THE J. OF BONE AND JOINT SURGERY, 1253 (2010).

[198] *See Moncivais*, *supra* note 185.

[199] *See* HAMPTON AND KING, *Knee Replacement Lawsuits – When Knee Surgeries Go Wrong*, https://www.hamptonking.com/blog/knee-replacement-lawsuits-when-knee-surgeries-go-wrong/ (last visited Apr. 19, 2023).

of the implant.[200] In many cases, the alleged defect caused the implant to fail early, resulting in additional surgery.[201]

The sheer number of these claims has caused many of the matters to be joined together into multidistrict litigation ("MDL").[202] This is a process whereby federal civil cases are consolidated into one court action. A single judge handles the litigation during the pretrial and discovery proceedings.[203] The matters retain their individual identity. Those that do not settle will be sent back to the federal courts in the states where the plaintiffs live.[204] About 15 percent of all civil litigation is part of multidistrict litigation. This consolidation may consist of thousands of separate lawsuits and many attorneys from around the United States to be placed in one MDL action.[205]

For instance, on October 7, 2022, the court consolidated all Exactech lawsuits involving defective knee implants into the Eastern District of New York to "serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation."[206] The court noted that "All actions can be expected to share factual questions concerning the design, manufacture, testing, marketing, packaging, and performance of the polyethylene components of their Exactech devices."[207]

These lawsuits stemmed from a recall dealing with the vacuum seal packaging that caused the knee replacements to fail prematurely.[208] Allegedly, the manufacturer failed to include a protective barrier that allowed oxygen to contaminate the polyethylene insert.[209] This omission caused the implant to degrade and lose its ability to function properly.[210] In the summer of 2021, the manufacturer recalled all its knee replacement units made after 2004. This Exactech action

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[200] *Id.*
[201] *See Moncivais*, *supra* note 185 at *2.
[202] *See id.* at *6.
[203] *See Will Exactech Joint Replacement Lawsuits Be Centralized In Mdl?,* NASH AND FRANCISKATO (July 14, 2022), https://nashfranciskato.com/blog/will-exactech-joint-replacement-lawsuits-be-centralized-in-mdl/.
[204] *See id*.
[205] *See Turner*, *supra* note 11.
[206] WILENTZ, *Status Update on Pending Exactech Multidistrict Litigation (MDL)*, https://www.wilentz.com/perspectives/drug-and-device-injury/2022-10-20-status-update-on-pending-exactech-multidistrict-litigation-mdl (last visited Nov. 22, 2022).
[207] In re Exactech Polyethylene Orthopedic Products Liab. Litig., MDL 3044, 2022 WL 5408779 (U.S. Jud. Pan. Mult. Lit. Oct. 7, 2022).
[208] *See Moncivais*, *supra* note 185 at *2.
[209] *See id*.
[210] *See id*.

affected almost 150,000 implants made in the United States.[211] If the plaintiffs can successfully demonstrate these units are defective, the financial implications are enormous. One source estimates that each claim will yield a settlement or verdict of between $70,000 to $400,000.[212]

Zimmer Biomet is another distributor that issued recall notices and ended up being sued. The company sent an announcement that the threads of its NexGen Complete Knee Solution Tibial Component may be "out of specification."[213] This recall affected more than 40,000 implants.[214] It was not the first time this company had a problem with its devices. In 2010, it recalled multiple components of a knee replacement product that allegedly caused pain and immune system reactions.[215] As consumers started filing claims, more than 1,000 lawsuits were consolidated into multi-district litigation in the District Court of Illinois.[216] It was alleged that the defendant's "high flex" femoral and tibial components used in knee replacement surgery are prone to premature loosening.[217] This defect was said to cause consumers to suffer pain, loss of knee movement, and revision surgery.[218] The defendant steadfastly denied that it did anything wrong, "including both design defect and failure to warn claims."[219]

The first case proceeding to trial resulted in a defense verdict. The factfinder concluded that the plaintiff failed to prove the device "was defectively designed and that the company failed to warn her about the potential dangers."[220] The defendant again prevailed in the second matter that went to trial.[221] The court determined that that the plaintiff did not satisfy its burden of proof that the design of the prosthetic was the proximate cause of the loosening.[222] This multi-district

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[211] *See* MILLER AND ZOIS, *Exactech Recall Lawsuit*, https://www.millerandzois.com/exactech-knee-implant-lawsuit.html#:~:text=Since%20it%20was%20founded%20in,implant%20systems%20manufactured%20after%202004 (last visited Nov. 22, 2022).

[212] *See Moncivais*, *supra* note 185.

[213] Michelle Llamas, *Zimmer Recalls 40,000 NexGen Knee Models,* DRUGWATCH (Jul. 13, 2020), https://www.drugwatch.com/news/2014/07/14/nexgen-knee-implant-recalled-zimmer/.

[214] *See id*.

[215] *See Moncivais*, *supra* note 185, at *7.

[216] *See Llamas*, *supra* note 213.

[217] *Id*.

[218] See In re: Zimmer Nexgen Knee Implant Products Liability Litigation, MDL No. 2272, (Oct. 1, 2012), https://www.jpml.uscourts.gov/sites/jpml/files/MDL-2272-Order_Vacating_CTO-09-12.pdf.

[219] Moll Law Group, *Judge Rules in Favor of Defense in Zimmer Biomet Defective NexGen Flex Knee Replacement Bellwether Lawsuit,* ILL. INJ. AND MASS TORT BLOG (Nov. 28, 2016), https://www.molllawgroup.com/blog/judge-rules-favor-defense-zimmer-biomet-defective-nexgen-flex-knee-replacement-bellwether-lawsuit/.

[220] *Id*.

[221] *Id*.

[222] *See id*.

litigation eventually resolved in June 2018, when it was announced that a settlement of the litigation had been achieved, but the terms of that agreement were sealed.[223]

These two manufacturers are merely examples of companies that have issued recalls or have been sued by dissatisfied knee replacement patients. More than 18 businesses have issued notices involving 300 knee implant devices over the years.[224] It is anticipated that the number of recalls will only increase as the industry continues to expand because of product demand. In addition, device manufacturers estimate that about one-third of its medical devices may fail or loosen intraoperatively or post-surgery.[225] Little wonder problems with knee prosthetics have spawned a cottage industry for litigation involving these products.

Firms brought into MDL can use a variety of strategies to reduce liability and depart the litigation as quickly as possible.[226] The bureaucratic quagmire of this complex litigation allows the defense to repeat useful themes, thereby establishing uniformity and credibility.[227] There are occasions when the seller will candidly acknowledge a problem with its product.[228] Other times, they will dig in for the long haul and vigorously defend the allegations to prevent bad publicity or the financial consequences.[229]

These are not easy cases, and questions arise about available insurance coverage and how that coverage may apply to the many claimed losses and their expenses.[230] However, manufacturers have vast sums of money available to defend these matters.[231] For example, Becton Dickinson and Company is a multinational medical technology company that manufactures and sells medical devices. Its annual revenues exceed $18.5 billion a year.[232] This revenue stream demonstrates the resources a pharmaceutical and medical device manufacturer may have at its disposal to defend an alleged defect in knee replacement litigation.[233] Even well-organized counsel for the plaintiffs, with strong common bonds and excellent litigation teams, have difficulty keeping pace with the volume of "paper" that can

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[223] *See Moncivais*, *supra* note 185 at *8.
[224] *See Pellerin*, *supra* note 192.
[225] *See id*. at *9.
[226] *See* Spiwe Jefferson et al. *7 Strategies to a Multidistrict Litigation Victory,* Docket (Apr. 20, 2020), https://docket.acc.com/7-strategies-multidistrict-litigation-victory.
[227] *See id*.
[228] *See Rieders*, *supra* note 194.
[229] *See id*.
[230] *See* Jeff Hines, *Winning Mass Tort Litigation Strategies,* TRIAL.COM, 213, 216 https://trial.com/wp-content/uploads/2020/03/Winning-Mass-Tort-Litigation-Strategies-IL-2011.pdf (last visited Dec. 14, 2022).
[231] *See Rieders, supra* note 194.
[232] *See BD Reports Fourth Quarter and Full Year Fiscal 2022 Financial Results* (Nov. 10, 2022), https://investors.bd.com/news-releases/news-release-details/bd-reports-fourth-quarter-and-full-year-fiscal-2022-financial.
[233] *See id*.

be generated by the manufacturers of medical devices and pharmaceuticals.[234] Afterall, these firms are among the wealthiest corporations in the world and are not intimidated by plaintiffs' lawyers.[235]

C. Ethical Issues in Multidistrict Litigation

The rules of ethics concerning client representation, settlement of claims and conflicts of interest were crafted with a single party and incident in mind.[236] If counsel represents more than one person in the same matter, potential conflicts arise. In addition, disparity involving the gravity of the injuries suffered by the claimants may foster dilemmas when the matter settles.[237] These ethical issues are only exacerbated in MDL.

Multidistrict litigation depends upon state law. That jurisprudence concerning warnings, product liability, recall, learned intermediary doctrine, and a host of other issues vary from state to state.[238] Counsel's understanding of the law in jurisdictions where there may be different rules can be a crucial factor in the success of the case.[239]

Choice of law requirements may mandate applying the state law where the plaintiff resides.[240] Lawyers in one state who accept clients from a jurisdiction where they are not admitted, can run into difficulties.[241] When lawyers accept thousands of cases, all of which may be legitimate, it is difficult to prosecute all of them. Rather, a key case will be tried. Still, others may be resolved on an algorithm or some other method of agreed values.[242] This process may be fair to most litigants in the MDL, but not to all of them. The result is that these matters may be remanded to the individual courts where the suits were initially filed.[243]

Many lawyers do not want to deal with the remanded case or the so-called "one off" case.[244] That is a complexity of multidistrict litigation. An ethical and competent lawyer will have a method for screening the cases they accept, being able to address local law issues, and dealing with matters on an individual basis if

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[234] *See Rieders*, *supra* note 194.
[235] *See id*.
[236] *See* Pete Kaufman, *Ethics Issues In Mass-Tort Litigation Settlements,* ADVOCATE, (Jan. 2014) https://www.advocatemagazine.com/article/2014-january/ethics-issues-in-mass-tort-litigation-settlements.
[237] *See id*.
[238] *Id*.
[239] *See id*.
[240] *See id*.
[241] *See Kaufman, supra* note 236.
[242] *See Rieders*, *supra* note 194.
[243] *See id*.
[244] *See id*.

they do not fit the mold of the settlement mechanism.[245] However, multidistrict litigation is a hornet's nest of ethical dilemmas because typically, a common fund will be created.[246] The lawyers and costs are then paid out of that fund. This money represents a percentage of the gross settlement before the client is compensated.[247]

D. Preemption

Patients filing claims over knee replacement devices will face various obstacles. One hurdle aggressively used by manufacturers is that the lawsuit is preempted by federal law.[248] The Food, Drug, and Cosmetic Act gives the FDA the power to regulate medical devices and cosmetics and to create benchmarks for foods.[249] This Act was revised in 1976 to include the Medical Device Amendments.[250]

Two ways exist for medical devices to gain approval by the FDA; they "may be approved through the Premarket Approval (["]PMA["]) method or be allowed by the 510(k) premarket notification process."[251] PMA demands scientific and regulatory proof that demonstrates the safety and usefulness of a device for its intended uses.[252] This method can be expensive and lengthy since it requires proper scientific evidence for approval.[253] On the other hand, the 510(k) premarket process is a quick and usually excludes medical devices from scientific trial mandates.[254] New products under this more relaxed method must be found "substantially equivalent" to established devices that have previously entered the market.[255]

The Medical Device Amendments expand the need for premarket approval to Class III devices.[256] This classification is "the most stringent regulatory

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[245] *See id*.
[246] *See id*.
[247] *See Rieders*, *supra note* 194.
[248] *See* HAUG PARTNERS LLP, *Clarifying the Scope of the Parallel Claim Exception to Federal Regulatory Preemption of Medical Devices,* JD SUPRA (Aug. 19, 2020), https://www.jdsupra.com/legalnews/clarifying-the-scope-of-the-parallel-20311/.
[249] *See* U.S. FOOD AND DRUG ADMIN., *80 Years of the Federal Food, Drug, and Cosmetic Act*, https://www.fda.gov/about-fda/fda-history-exhibits/80-years-federal-food-drug-and-cosmetic-act (last visited Apr. 19, 2023).
[250] U.S. FOOD AND DRUG ADMIN., *A History of Medical Device Registration and Oversight in the United States*, https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states (last visited Apr. 18, 2023).
[251] *Pellerin*, *supra* note 192.
[252] *See id*.
[253] *See id*.
[254] *See id*.
[255] *Id*.
[256] *See HAUG PARTNERS LLP*, *supra* note 248.

category for medical devices."[257] Implantable pacemakers and breast implants are examples of items that fall within this category.[258] A device with this designation may only enter the marketplace following an FDA assessment that finds the product has demonstrated a "reasonable assurance of safety and effectiveness."[259] Knee implants initially received a Class III designation which required premarket approval.[260] However, in 1999, the FDA lowered the classification for many knee implant products to Class II, which category is reserved for safer products like blood pressure cuffs, syringes, contact lens, and surgical gloves.[261] The agency approves most Class II products by using the Premarket Notification 510(k) process.[262] This classification means that the device is safe and effective and equal to another medical item already on the market.[263]

The reclassification avoids the scrutiny of a Class III investigation which requires the applicant to show that the product is safe and effective through "the development of a data-driven benefit/risk profile."[264] This method requires clinical trials to produce sufficient data analyses.[265] The designation of a product as a Class II device is important because lawsuits are no longer barred by the preemption doctrine in state court actions,[266] "absent regulation other than identification regulation."[267] A preemption clause is contained in the Medical Device Amendments:

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[257] *Id*.

[258] *See* U.S. FOOD AND DRUG ADMIN., *Learn if a Medical Device Has Been Cleared by FDA for Marketing*, https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing#:~:text=Class%20III%20%E2%80%93%20These%20devices%20usually,devices%20fall%20under%20this%20category (last visited Apr. 19, 2023).

[259] *See HAUG PARTNERS LLP*, *supra* note 248.

[260] *See* U.S. FOOD AND DRUG ADMIN., *Medical Devices; Reclassification of The Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis and The Knee Joint Femorotibial (Unicompartmental) Metal/Polymer Porous-Coated Uncemented Prosthesis. Final Rule*, PUBMED.GOV (Mar. 24, 2003), https://pubmed.ncbi.nlm.nih.gov/12653113/.

[261] *See* Robert Fenton, *The 3 FDA Medical Device Classes [Differences and Examples Explained*], QUALIO (Oct. 29, 2021), https://www.qualio.com/blog/fda-medical-device-classes-differences#:~:text=The%20FDA%20defines%20Class%20II,and%20effectiveness%20of%20the%20device.%E2%80%9D.

[262] *See id*.

[263] *See id*.

[264] *Id*.

[265] *See id*.

[266] *See* Kevin R. Costello et al., *Regulatory Preemption of Medical Devices,* FINDLAW (May 19, 2016), https://corporate.findlaw.com/litigation-disputes/regulatory-preemption-of-medical-devices.html#:~:text=Thus%2C%20as%20a%20general%20rule,be%20preempted%20from%20state%20actions. *But see* Degelmann v. Advanced Med. Optics Inc., 659 F.3d 835 (9th Cir. 2011) (preempting a claim involving contact lens solution even though the item was a Class II product).

[267] Anguiano v. E.I. DuPont De Nemours & Co., Inc., 44 F.3d 806 (9th Cir. Ct. App. 1995).

> No state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use and requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.[268]

This provision has been construed by the Supreme Court "to preempt most common-law duties."[269] The Court's rationale is that state-law tort claims would obstruct the mandates implemented by the FDA for a Class III device requiring premarket approval.[270] Preemption, however, is not a complete bar to all state law remedies that parallel federal legislation.[271] As noted in *Haudrich v. Howmedcia, Inc.,* Congress did not intend to preempt common law tort actions by enacting the Medical Device Amendments."[272]

The success of this preemption defense is not guaranteed, and the doctrine has been applied inconsistently with different court interpretations.[273] For instance, federal circuit courts are split concerning the scope and interpretation of this preemption. Some have allowed plaintiffs to pursue state law actions while others bar these claims.[274] *McNeil-Williams v. DePuy Orthopaedics, Inc.* provides an example.[275] This litigation involved a matter where the FDA obtained premarket approval for a knee implant.[276] This action was followed by the defendant's notice to the FDA of various changes to its implants.[277] Several years later, the plaintiff received one of these knee implants which allegedly proved to be defective requiring revision surgery.[278]

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[268] 21 U.S.C. § 360k(a).
[269] Howard v. Sulzer Orthopedics, Inc., 382 F. App'x 436, 437 (6th Cir. 2010).
[270] *See id*.
[271] *Id*. at 440.
[272] Haudrich v. Howmedica, Inc., 169 Ill. 2d 525, 535, 662 N.E.2d 1248 (Ill. 1996).
[273] *HAUG PARTNERS LLP, supra* note 248. A roadmap concerning the viability of express and implied preemption for a medical device is found in Andrew Tauber, Max Heerman and Brian Wong, *How to Argue Medical Device Preemption, mayerbroun.com,* https://www.mayerbrown.com/-/media/files/news/2012/11/how-to-argue-medical-device-preemption/files/how-to-argue-medical-device-preemptionfor-the-defe/fileattachment/how-to-argue-medical-device-preemptionfor-the-defe.pdf (last visited Nov. 24, 2022).
[274] In re Sulzer Hip Prosthesis & Knee Prosthesis Liab. Litig., 2006 U.S. Dist. LEXIS 10712 (N.D. Ohio Mar. 14, 2006).
[275] McNeil-Williams v. DePuy Orthopaedics, Inc., 384 F. Supp. 3d 570 (E.D.N.C. 2019).
[276] *Id*. 571.
[277] *Id*. at 572.
[278] *Id*.

The plaintiff instituted suit and alleged negligence in the design and labeling of the prosthetic. McNeal-Williams claimed that the defendant failed to warn the FDA of the risks of the device.[279] *DePuy Orthopaedics, Inc.* moved for summary judgment arguing that the lawsuit was preempted by the government's approval of the device under the Medical Device Amendments.[280] It asserted that only the government could institute suit for noncompliance with the legislation.[281] The lower court agreed, and this ruling was upheld on appeal. It was noted that North Carolina law does not require manufacturers to notify the FDA of adverse reactions and risks associated with the device.[282] That duty of notification only extends to consumers and physicians.[283]

A claim for a defective knee implant was not preempted in *Howard v. Sulzer Orthopedics, Inc.*[284] The plaintiff received a knee implant made by the defendant through a new manufacturing process that inadvertently permitted machine oil to remain on the device.[285] This contamination caused the prosthetic not to bond with the bone, and the plaintiff had to have revisions surgery.[286] Litigation ensued, and the claimant alleged negligence per se in the failure of Sulzer Orthopedics, Inc. to follow the FDA premarket- approved manufacturing process.[287] The district court granted the defendant's motion for summary judgment finding that it did not have to take any additional steps in the production process that had not already gained FDA premarket approval.[288] Therefore, the claim was preempted by the Medical Device Amendments.[289] The court found that the manufacturer only had to comply with a validated cleaning process. The law did not mandate a specific result, i.e., the removal of the oil.[290]

This determination was reversed on appeal.[291] The FDA mandates require the actual removal of the contaminate and that risk should remain with the manufacturer and not the patient.[292] The FDA may demand an implant be kept oil-free, but a state may also provide a damages remedy for violations of an identical state requirement."[293]

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[279] *Id*.
[280] *DePuy Orthopaedics, Inc.,* 384 F. Supp. 3d at 575.
[281] *Id*.
[282] *Id*.
[283] *Id*.
[284] Howard v. Sulzer Orthopedics, Inc., 382 F. App'x 437, 438 (6th Cir. 2010).
[285] *Id*.
[286] *Id*.
[287] *Id*.
[288] *Id*. at 442.
[289] *Sulzer Orthopedics, Inc.,* 382 F. App'x at 442.
[290] *Id*. at 438.
[291] *Id*. at 441.
[292] *Id*.
[293] *Id*.

Not all products used in knee replacement surgery are subject to the preemption defense, especially if they enjoy an FDA Class II classification. Bone cement is an example. This compound is subject to FDA control under the Medical Device Amendments to the Food, Drug, and Cosmetic Act.[294] Its formal name is polymethyl methacrylate (PMMA). The cement enjoys widespread adoption in implant fixations.[295] The product is an acrylic polymer that acts like grout to establish "a tight space which holds the implant against the bone."[296] It is not an adhesive. Still, it utilizes a close meshing between the bone's surface and the implant.[297] Its consistency allows substances to be added like antibiotics. This infusion system delivers the medicine directly to the surgical site to help reduce infections.[298] The product was originally labeled as a Class III device which required pre-market approval by the FDA.[299] This classification meant the preemption defense could be asserted to lawsuits by patients when the cement allegedly caused the harm.[300]

As a word of caution, the FDA is not the insurer of a product's safety despite the classification's mandates. This agency is responsible for the oversight of more than $2.8 trillion in food consumption, medical products, and tobacco. There are more than 6,700 different medical device product categories.[301] Only 10 percent of the FDA's total budget is spent on Devices and Radiological Health regulatory activities, and only 34 percent of those costs are paid for by industry user fees.[302] Therefore, the certification process can be overwhelming for the FDA. One might say that the review process consists of nothing more than a "notification" of the product rather than any meaningful review. Indeed, a significant number of medical devices bypass the FDA's normal premarket approval process by submitting a § 510(k) notification.[303]

Studies also reveal that the cost of patient care and litigation can be driven by the efforts of the medical healthcare industry to sell products, devices, drugs,

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[294] *DePuy Orthopaedics, Inc.,* 384 F. Supp. 3d at 575.
[295] Raju Vaishya, Mayank Chauhan, & Abhishek Vaish, *Bone Cement*, 4 J. CLIN. ORTHOP. TRAUMA 157 (Dec. 15, 2013), 10.1016/j.jcot.2013.11.005.
[296] *Id*.
[297] *Id*.
[298] *Id*. at 158.
[299] Thompson v. DePuy Orthopedics, 2015 WL 7888387 1, 3 (S.D. Ohio 2015).
[300] James M. Beck, *Medical Device Preemption and Downclassification,* DRUG AND DEVICE LAW (Oct. 7, 2010), https://www.druganddevicelawblog.com/2010/10/medical-device-preemption-and.html.
[301] U.S. FOOD & DRUG ADMINISTRATION, *FDA at a Glance*, https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance (last visited Apr. 19, 2023).
[302] *Id.* For disclosure purposes, Mr. Rieders and Coffiner are the same person, currently a senior associate with the law firm for Amici Curiae.
[303] Medtronic, Inc. v. Lohr, 518 U.S. 470, 478 (1996).

and pharmaceuticals.[304] Cases involving product liability law in the context of medical devices are illustrative of the difficulty of holding medical device manufacturers accountable for defective products.[305] Also, the Federal Food & Drug Administration cannot be counted upon to protect the patient. As stated in the amicus curiae brief in *Melissa Ebert v. C.R. Bard, Inc.,* "Strict reliance on the FDA to police manufacturers and safeguard the public is likely to jeopardize the consumer/patient given the limited resources of the FDA, its sometimes revolving-door environment, and the political pressures brought to bear by the medical device industry."[306] Even the United States Supreme Court opined "product clearance accomplished through the 510(k) process as 'a qualification for an exemption rather than a requirement.' … in part because the 'process impose[s] no requirements with respect to the design of the device.'"[307]

Statistics reveal that a more significant number of knee arthroplasty devices approved by the 510(k) process are recalled as contrasted to implants endorsed by the more rigorous PMA process.[308] Perhaps altering the 510(k) procedure may facilitate manufacturers to improve the safety of their products.[309]

E. Causes of Action

Lawsuits involving knee replacements are not limited to product liability, breach of warranty, or malpractice claims. They may arise in various contexts, such as disability, worker's compensation, and personal injury lawsuits. A Westlaw search reveals 7,028 reported cases and more than 10,000 administrative decisions involving knee replacement surgeries.[310] Not surprisingly, a google search of "knee replacement litigation" shows many advertisements and attorney websites dealing with the topic.

The following is a representative sampling of cases.

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[304] See e.g., Ray Moynihan, Iona Heath, and David Henry, Selling Sickness: The Pharmaceutical Industry and Disease Mongering, BMJ. 2002 Apr 13; 324(7342): 886–891, doi: 10.1136/bmj.324.7342.886.

[305] *Rieders*, *supra* note 194.

[306] Melissa Ebert v. C.R. Bard, Inc., Docket No. 26EAP 2021, Brief of Amici Curiae Gross, et al., on Petition for Certification of Question of Law in the United States Court of Appeals for the Third Circuit, p. 7.

[307] Cisson v. C.R. Bard, Inc. (In re C.R. Bard, Inc.), 810 F.3d 913, 921 (4th Cir. 2016) (internal citations omitted).

[308] *Pellerin*, *supra* note 192.

[309] *Id*.

[310] This figure is based upon a Westlaw search of the term "knee replacement" conducted on November 13, 2022.

1. Bone Cement Infused with Antibiotics

The risk of infection makes it standard practice to use antibiotics during joint replacement surgery.[311] The insertion of a foreign device in the body enlarges the danger of deep infections because of "bacterial colonization and biofilm formation on implant surfaces."[312] While infections occur in only 0.5% to 3% of cases, they can lead to death and must be viewed as a serious complication of joint replacement surgery.[313] Perioperative antibiotic use shortly before surgery has been shown to lower microbial shelf life and growth from surgical areas and to lower the incidence of staphylococcus aureus.[314] The American Academy of Orthopedic Surgery recommends antibiotics administration for all joint replacement surgeries "prior to any invasive procedure that may cause bacteremia."[315] In this regard, it is suggested that patients take antibiotics orally one hour before surgery.[316]

Some physicians use bone cement laden with antibiotics because it releases a high antibiotic concentration at the operative site.[317] This practice has gained worldwide adoption for more than 30 years as a preventative application with orthopedic implants.[318] However, FDA approval is limited to low-dose antibiotic use.[319] Enlarging the viscosity of bone cement may cause a greater heat-releasing response, possibly causing thermal harm to bone and lower interference depth.[320]

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[311] Christof Berberich & Pablo Sanz-Ruiz, *Risk Assessment Of Antibiotic Resistance Development By Antibiotic-Loaded Bone Cements: Is It A Clinical Concern?,* 4 EFFORT OPEN REV. 576 (Oct. 11 2019), 10.1302/2058-5241.4.180104.

[312] *Id*.

[313] Javier Martínez-Moreno, et al., *Antibiotic-loaded Bone Cement as Prophylaxis in Total Joint Replacement,* WILEY ONLINE LIBR. (Nov. 27, 2017), https://onlinelibrary.wiley.com/doi/full/10.1111/os.12351.

[314] C. Ronald MacKenzie, et al., *Perioperative Care of the Orthopedic Patient*, 2020, ISBN: 978-3-030-35569-2, pgs. 327-41.

[315] Mary Ann Porucznik, *AAOS Releases New Statement on Antibiotics After Arthroplasty*, AM. ACAD. OF ORTHOPEDIC SURGEONS (May 1, 2009), https://www.aaos.org/aaosnow/2009/may/cover/cover2/.

[316] Robert Mayle, Jr., *Antibiotic Prophylaxis Protocol After Total Joint Replacement,* https://www.robertmaylemd.com/antibiotic-prophylaxis-protocol-after-total-joint-replacement.html (last visited Nov. 14, 2022).

[317] Ryuji Mori, et al., *Increased Antibiotic Release from a Bone Cement Containing Bacterial Cellulose*, Clinical Orthopedics and Related Research, 600-06 (Feb. 2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3018194/.

[318] Arlen D. Hanssen, *Prophylactic Use of Antibiotic Bone Cement an Emerging Standard—In Opposition,* 19 THE J. OF ARTHROPLAST. 4, 73 Suppl. 1 (2004).

[319] C.J. Gutowski, et al., *The Economics of Using Prophylactic Antibiotic-Loaded Bone Cement in Total Knee Replacement*, THE BONE & JOINT J., 96-B, (Jan. 2014).

[320] *Id*.

This change may diminish the strength of the bond.[321] Therefore, the use of antibiotic cement in primary knee replacements is controversial because of the development of antibiotic resistance over time as well as other complications.[322] Some say that cement containing high levels of antibiotics may even increase the chance that the implant will loosen because the mechanical properties of the cement are altered.[323]

Thompson v. DePuy Orthopedics involves a knee replacement where bone cement was infused with Gentamicin.[324] The court noted that bone cement is a liquid and powder compound that is mixed in the operating room.[325] The cement is not considered an adhesive but acts as grout between the implant and bone.[326] The cement is a class II device regulated by the Food and Drug Administration and must satisfy specific standards required by this government agency.[327] In this matter, the defendant obtained approval from the FDA to alter the antibiotic laced bone cement to change the polymethyl methacrylate content to 84.73%.[328]

The plaintiff underwent a partial knee replacement four years after this change, and the surgeon used the new mixture of bone cement with Gentamicin.[329] The patient made an uneventful recovery. Two years later, however, she developed discomfort and swelling in her knee.[330] A bone scan revealed the device had loosened because of cement failure at the cement/bone junction.[331] Revision surgery was needed, and the surgeon found loosening of both the tibial and femoral components of the prosthetic.[332]

Suit was instituted against the defendant as the seller of the product.[333] The surgeon testified that the "Gentamicin bone cement failed at a higher rate than

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[321] Leonard Buller, et al., *Primary Total Knee Arthroplasty Performed Using High-Viscosity Cement is Associated with Higher Odds of Revision for Aseptic Loosening,* 35 THE J. OF ARTHROPLASTY 6 182-89 (June 2020).

[322] *Martínez-Moreno*, *supra* note 313.

[323] *Limited Evidence Suggests the Use of Antibiotics in the Cement May Reduce the Risk of Periprosthetic Joint Infections For Patients Undergoing Cemented Total Hip Arthroplasty (THA),* AAOS, https://www.orthoguidelines.org/go/cpg/detail.cfm?id=1512#:~:text=Although%20the%20studies%20did%20not,properties%20of%20the%20cement%20fixation (last visited Nov. 14, 2022).

[324] *Thompson*, 2015 WL 7888387 at 3.

[325] *Id*. at 1.

[326] *Id*.

[327] *Id*.

[328] *Id*. at 2-3.

[329] *Thompson*, 2015 WL 7888387 at 2-3.

[330] *Id*. at 3.

[331] *Id*.

[332] *Id*.

[333] *Id*.

expected and the risks of the product outweighed the benefit."[334] An expert in bone cement noted the implant loosened because the antibiotic bone cement failed to correctly connect the implant to the bone.[335] He went on to state that implants fail because of factors relating to the patient, surgery, or device.[336] The expert then opined that the device loosened because "the viscosity of the DePuy bone cement changed after non-micronized Gentamicin was introduced," and the viscosity of the new cement mixture "was too high requiring a deviation from the manufacturing specifications."[337] This variation allegedly created a design and manufacturing defect.[338]

The defendant filed a motion for summary judgment which the court denied in part. The manufacturer asserted that the claim was barred because of federal preemption that bars state and local claims pertaining to medical devices.[339] The court disagreed and noted that the alteration in the cement was only a reclassification and the FDA never considered the safety or efficacy of micronized or non-micronized Gentamicin that are related to the design or manufacturing of the product.[340] The court denied the motion since it found sufficient circumstantial evidence existed of a manufacturing defect to deny the motion.[341] The plaintiff's experts testified that a knee replacement is expected to last ten to twenty years. In this case, it failed after a few years. The surgeon also noted that since he switched to a different bone cement, he has had no incidents of loosening.[342] The court did dismiss the counts dealing with an inadequate warning, fraud, negligent misrepresentation, and punitive damages.[343]

In *Henderson v. Dasa*, the plaintiff underwent a knee revision to replace an existing prosthetic made by Stryker Corporation.[344] The patient claimed that when the prosthetic left the defendant's control, the product contained expired antibiotic bone cement.[345] This alleged defect caused the knee implant to loosen.[346] The manufacturer countered that the expiration date only applied to the antibiotic and the bone cement was not defective.[347] The court denied the defendant's motion for summary judgment and noted that a sufficient cause of action had been stated since

[334] *Thompson*, 2015 WL 7888387 at 4.
[335] *Id*. at 5.
[336] *Id*.
[337] *Id*. at 6.
[338] *Id*. at 7.
[339] *Thompson*, 2015 WL 7888387 at 7.
[340] *DePuy Orthopedics,* 2015 WL 7888387 at *8.
[341] *Id*. at *11.
[342] *Id*. at *14.
[343] *Id*.
[344] Henderson v. Dasa, No. CIV.A 13-8, 2014 WL 1365968, at *1 (E.D. La. Apr. 7, 2014).
[345] *Id*. at *2.
[346] *Id*.
[347] *Id*.

it was alleged that the defendant knew that the antibiotic bone cement had expired when it left its custody, and the seller made no effort to notify the plaintiff or her surgeon of the dangers related to the expired cement.[348] The court, however, did dismiss the breach of warranty claim since the complaint contained no evidence concerning the contents of such a guaranty.[349]

F. Knee Replacement and Malpractice

Medical malpractice is a recognized tort in the United States. While the volume of claims requiring payment in recent years has declined, the average disbursement has increased and varies by state.[350] A cause of action requires the patient to prove that the health care provider negligently rendered care and that negligence was the proximate cause of the injury.[351] One study discovered that the most frequent causes of a malpractice claim for primary TKA were chronic pain or dissatisfaction, followed by nerve palsy, postoperative in-hospital falls, deep vein thrombosis and pulmonary embolism.[352] The average settlement or verdict was $325,369, with $2.42 million representing the largest award. The average cost in defending a claim was $66,365.[353]

A medical malpractice case, typically against a physician, is a problematic case to advance.[354] The knee is a highly complex structure and is subject to significant stresses and strains from movement, occupation, weight, and the aging process.[355] Physicians often maintain that the knee is incapable of being restored to normal through surgery or replacement, given the forces that it must withstand.[356] As noted by one orthopedic surgeon, "if I had my way, and if my hospital employer would permit, physicians would send every knee patient home, tell them to lose 25 pounds and come back in a year."[357] A number of these patients should not be subject to surgical intervention, but the demand to "fix me, doctor" is overwhelming.[358]

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[348] *Id*.
[349] *Dasa*, 2014 WL 1365968 at *3.
[350] JUSTPOINT, *US Medical Malpractice Statistics*, https://justpoint.com/knowledge-base/us-medical-malpractice-case-statistics (last visted Feb. 12, 2023).
[351] B. Sonny Bal, *An Introduction to Medical Malpractice in the United States.* CLIN. ORTHOP. RELAT. RES,. 339, 339–47 (2009).
[352] Diana Patterson, et al., *Lawsuits After Primary and Revision Total Knee Arthroplasty: A Malpractice Claims Analysis,* J. AM. ACAD. ORTHOP. SURG. (2017).
[353] *Id*.
[354] *Rieders, supra* note 194.
[355] *Id*.
[356] *Id*.
[357] *Id*.
[358] *Id*.

An example of a medical malpractice claim involving a knee replacement is *Blendowski v. Wiese.*[359] A lawsuit was filed against a resident physician who severed the plaintiff's peroneal and tibial nerves while drilling into the femur during knee replacement surgery.[360] This claim was dismissed because a resident who assists a surgeon during an operation and does not employ independent judgment is not liable as long as the supervisor's instructions "did not so greatly deviate from normal practice that the resident should be held liable for failing to intervene." [361] The undisputed facts demonstrate that the surgeon dictated the procedure to be performed and the location and angle of the drill.[362] Therefore, the defendant did not use independent medical judgment.[363]

In *Heubish v. Baez*, the plaintiff underwent a total knee replacement.[364] It was claimed that the surgeon did not correctly size the knee implant, overstuffed the knee, and failed to exercise the proper postoperative care.[365] These deviations caused the need for revision surgery.[366] The jury found in favor the defendant and that decision was appealed. [367]

The higher court upheld his finding. The surgeon's habit testimony demonstrated that he operated the same way from patient to patient. His practice for measuring and dissecting 10 millimeters of the plaintiff's kneecap was consistent with his prior performance standards and was carried out deliberately and similarly on every patient.[368] Therefore, this testimony was properly admitted and supported a finding that the surgeon was not negligent. [369]

G. Knee Replacement and Informed Consent

A knee replacement is a relatively safe procedure, but complications can occur. Setting aside the general risks of surgery, these perils include wound infection, unexpected bleeding, soft tissue or nerve damage, blood clots, a bone fracture around the artificial joint, excessive scar formation, chronic knee pain, and an allergic reaction to the prosthetic.[370] Statistically, most people are happy with

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[359] Blendowski v. Wiese*,* No. 17-00599, slip op. at *1 (N.Y. App. Div., 2018).
[360] *Id*.
[361] *Id*. at *2.
[362] *Id*.
[363] *Blendowski*, 158 A.D. 3d at 1286.
[364] Heubish v. Baez*,* 113 N.Y.S. 3d 755, 756 (N.Y. S. CT. 2019).
[365] *Id*. at 757.
[366] *Id*. at 757.
[367] *Id*.
[368] *Id*.
[369] *Heubish*, 113 N.Y.S. 3d at 757.
[370] NHS, *Risks-Knee Replacement*, https://www.nhs.uk/conditions/knee-replacement/risks/ (last visited Nov. 14, 2022).

their intervention and the general satisfaction rate one-year post-surgery is 77.8%.[371] While significant advances in surgical methods and prostheses have occurred, 20% of TKA recipients are displeased following their operation, and this rate has not changed over time.[372] Continued pain, restricted function, poor patient selection and surgical technique, malalignment of limbs, and postoperative difficulties are the most common reasons for this displeasure.[373]

These risks make it essential for the surgeon to discuss the procedure's complications and likely outcomes with the patient. This process, known as informed consent, is an ethical and legal requirement imposed upon physicians. [374] The doctrine stems from a patient's right to dictate what happens to their body.[375] When patients are dissatisfied with their surgery or suffer an adverse consequence, lack of informed consent is one theory of liability advanced by the aggrieved party. *Smith v. Lincoln General Hospital* is an example of an informed consent case.[376] In this matter, the patient knee replacement failed because of an infection.[377] This complication generated a lawsuit for the defendant's failure to properly inform the patient of the risks of the surgery. The plaintiff had rheumatoid arthritis and was a heavy drinker and smoker.[378] The patient was told that both knees had to be replaced, and he had a "5–10% chance of significant complications, including infection."[379] Smith had both knees replaced one week apart and was given antibiotics each time a few days before the operations.[380] However, soon before the right knee replacement, the surgeon learned the middle of the patient's knee contained a lesion which is common in those with rheumatoid arthritis.[381] The doctor believed this was an old finding posing no additional risk, so he proceeded with the surgery by cutting around the lesion and inserting the implant.[382]

A few days later, the plaintiff developed a temperature, an elevated white blood cell count, and a rapid pulse. The physician believed these developments were normal postoperative findings and did not indicate an infection.[383] Two weeks later, an indentation was discovered along the

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[371] Mieralimu Muertizha, et al., *Factors Contributing To 1-Year Dissatisfaction After Total Knee Arthroplasty: A Nomogram Prediction Model,* J. OF ORTHOPAEDIC SURGERY AND RSCH., 1 (2022).
[372] *Id*. at 2.
[373] *Id*.
[374] Parth Shah, et al., Informed Consent, NAT'L LIBR. OF MED. (Jun. 11, 2022), https://www.ncbi.nlm.nih.gov/books/NBK430827/.
[375] *Id*.
[376] Smith v. Lincoln Gen. Hosp., 658 So.2d 256, 259 (La. App. 1995).
[377] *Id*.
[378] *Id*.
[379] *Id*.
[380] *Id*.
[381] *Smith*, 658 So.2d at 259.
[382] *Id*.
[383] *Id*.

incision line.[384] The defendant prescribed antibiotics to treat the problem, but no wound culture was taken. The next day, a visiting nurse discovered the area was very red and had a foul odor.[385] Nine days elapsed, and no one came to the patient's home to check the wound. When the knee was finally examined, two holes were present, along with a yellow discharge.[386] A reexamination of the knee by a nurse occurred two weeks later, and the wound was described as "healed." While the two holes were still present, the knee had no drainage, redness, or swelling.[387]

The plaintiff subsequently saw the surgeon for his first post-surgery visit, and the doctor discovered an ulcer on the patient's knee with "necrotic debris." While the physician was concerned about finding the ulcer, blood tests were normal, so the surgeon did not suspect an infection.[388] One month later, the patient's pain increased, and he returned to the doctor's office. At this time, a deep-seated infection of the joint was diagnosed.[389] Aggressive intravenous antibiotic treatments were started, but the implant could not be saved, and the knee had to be fused.[390]

Litigation ensued, and the judge charged the jury that malpractice occurs "when a physician fails to disclose relevant information to the patient, and this failure to disclose causes damage to the patient."[391] The jury found in favor of the doctor, and the patient claimed that there was an error because the physician did not tell him of the increased chance of infection because the patient had rheumatoid arthritis and drank and smoked heavily.[392] He also claimed that a reasonable person would not have submitted to the operation had he been adequately advised of the increased risk.[393]

On appeal, the court upheld the finding for the defendant. It noted that when the situation allows, a patient should be informed of the character of the condition, the nature of the suggested treatment, the attendant risks, chances of success, and alternate methods of treatment.[394] In this case, all of the experts agreed that those with rheumatoid arthritis who smoke and drink heavily are more likely to develop an infection than healthy patients.[395] An infection, in this case, was a material risk of which the plaintiff should have been told. The plaintiff claimed that while the

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[384] *Id*. at 260.
[385] *Id*.
[386] *Smith,* 658 So.2d at 260.
[387] *Id*.
[388] *Id*. at 261.
[389] *Id*.
[390] *Id*.
[391] *Smith,* 658 So.2d at 262.
[392] *Id*. at 262-63.
[393] *Id*. at 263.
[394] *Id*.
[395] *Id*.

surgeon may have revealed some risks of infection, he was negligent for not disclosing that the risk was as high as 15–30%.[396] The patient admitted that the surgeon noted that the risk was as high as 10%. Simply put, the jury found in favor of the defendant because it accepted the defendant's explanation of the risk level.[397]

H. Revision Surgery

A Westlaw search of jury verdicts and settlements for knee revisions disclosed 75 cases in which an award was rendered over five million dollars.[398] On the other hand, 1,607 cases were reported in which no money was given.

Cipriani v. Valley Hospital is an unusual case in which a surgeon treated the plaintiff for knee pain that resulted in a knee replacement.[399] This intervention did not control the discomfort, and the patient was told that she might need knee revision surgery. However, following a course of physical therapy, her pain diminished until she fell and twisted her knee.[400] Because her knee swelled, she returned to the surgeon, and a knee revision was performed.[401] According to the patient, the doctor only told her that the revision surgery "was much more serious."[402] When the post-surgical pain failed to abate, x-rays, an MRI, and a bone scan were performed, which were normal.

Several months later, the plaintiff developed severe pain in her leg while at work that "felt like an explosion."[403] A medical workup discovered a stress fracture.[404] This new development prevented her from working, and she had to use a scooter and wheelchair to ambulate.[405] Following a second opinion that confirmed the diagnosis, the patient underwent another knee revision which left her with a limp and unable to work.[406] This situation caused financial distress, and she had to remortgage her home.[407]

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[396] *Smith,* 658 So.2d at 262-63.
[397] *Id*. at 264.
[398] This number is based upon a Westlaw search using "knee revision surgeries" in the search engine. This search was conducted on Nov. 14, 2022).
[399] Cipriani v. Valley Hosp., No. A-3836-16T3, 2019 WL 1224624, at *1 (N.J. Super. Ct. App. Div. Mar. 15, 2019).
[400] *Id*. at *3.
[401] *Id*.
[402] *Id*.
[403] *Id*. at *5.
[404] *Cipriani,* 2019 WL 1224624, at *5.
[405] *Id*.
[406] *Id*. at *5-6.
[407] *Id*. at *6.

The plaintiff sued the surgeon, and her expert opined that the physician was negligent because of the incorrect placement of the prosthetic, and this misalignment caused the premature loosening of the implant.[408] He further noted that revisions fail more frequently than in initial replacement surgery at the rate of 2% a year, even when the surgeon "does everything correctly." With knee revisions, 20% of patients will have continued knee pain.[409] At the conclusion of the evidence, the jury found in favor of the defendant, and the plaintiff appealed.[410]

On appeal, the patient attacked the judge's ruling prohibiting the mentioning of a $2,500 check the doctor gave the plaintiff at her visit following the second revision surgery.[411] The defendant admitted that he issued the check but said he gave it to the plaintiff because she was upset about her situation and inability to pay her debts.[412] According to the surgeon, his actions were a show of compassion because the patient had been with him for so many years.[413] The trial judge excluded this evidence because he thought its probative value substantially outweighed its undue prejudice.[414] The plaintiff countered that the check was an admission of liability and to keep the doctor in good graces with the patient.[415] The appellate court disagreed and noted that the ruling to admit or exclude the check was within the trial court's sound discretion.[416] Furthermore, the check was neither an offer to compromise pursuant to settlement negotiations nor an admission of liability.[417] The court found that the check was merely intended to help the patient pay her mortgage while recovering from the stress fracture. [418]

I. Worker's Compensation

The premise of workers' compensation is to compensate a person hurt at work or who becomes ill because of their employment.[419] These benefits are paid

[408] *Id*. at *2.
[409] *Cipriani,* 2019 WL 1224624, at *3.
[410] *Id*.
[411] *Id*.
[412] *Id.*
[413] *Id*.
[414] *Cipriani,* 2019 WL 1224624, at *6.
[415] *Id*.
[416] *Id*.
[417] *Id*.
[418] *Id*.
[419] N.Y. STATE WORKERS' COMP. BD., *What is Workers' Compensation*, http://www.wcb.ny.gov/content/main/Workers/what-is-workers-compensation.jsp (last visited Nov. 15, 2022).

regardless of fault.[420] The purpose of this law is to safeguard employers and their workers from monetary loss, and benefits are awarded to defray medical expenses, lost wages, and funeral costs.[421] The initial burden of proof is upon the claimant to show the medical problem is work-related. Nevertheless, many states have presumptions that shift the burden of proof to the employer to disprove the causal connection for certain types of diseases and claimants.[422] However, these inferences are "rebuttable," and the employer is permitted to "argue against the presumption."[423]

A common defense related to knee replacement surgery is that the intervention was not caused by a work-related accident but is the result of preexisting arthritis or degeneration.[424] This defense has been met with varying degrees of success, as demonstrated by the following cases.

Moore v. Sleepy Creek Farms involves a worker who sustained a compensable right knee injury when hit by boxes that struck his leg.[425] Following unsuccessful arthroscopic surgery, he underwent a right knee replacement six months later.[426] The claimant's treating physician noted that while the worker had preexisting arthritis and chronic osteonecrosis conditions, the accident aggravated and accelerated these problems resulting in severe pain and the need for knee replacement.[427] The employer denied the TKA was related to the industrial accident.[428]

The court found in favor of the plaintiff.[429] It noted that where a claimant's initial injury is deemed compensable, there is a presumption that any additional medical treatment is related to the accident. The employer must then rebut that presumption.[430] In this case, the court noted that just because a preexisting condition may have partially caused an employee's

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[420] *Id*.
[421] THE HARTFORD, *Top 10 Workman's Comp Questions,* https://www.thehartford.com/workers-compensation/questions-answered (last visited Nov. 15, 2022).
[422] AM. ACAD. OF ACTUARIES, *Presumptive Benefits in Workers' Compensation*, https://www.actuary.org/sites/default/files/2020-06/IB_COVIDworkers_comp_2.pdf (last visited Nov. 15, 2022).
[423] *Id*.
[424] Jeffrey Kaufman, *Does Workers' Compensation Cover A Total Knee Replacement?* MICH. WORKERS COMP. LAWYERS (Jul. 2, 2020), https://www.workerscomplawyerhelp.com/blog/2020/07/workers-compensation-total-knee-replacement/.
[425] Moore v. Sleepy Creek Farms/Goldsboro Milling Co., No. COA09–1243, 2010 WL 2816639, at *1 (N.C. Ct. App. July 20, 2010).
[426] *Id*. at *2.
[427] *Id*.
[428] *Id*.
[429] *Id*.
[430] *Moore*, 210 WL 2816639, at *4.

TKA, it did not preclude recovery.[431] The facts show that the worker had no problems with his knee before the accident, and the work-related injury accelerated the condition leading to the knee replacement.[432]

A contrary result was reached in *Pearson v. Archer-Daniels-Midland Milling Co*mpany.[433] Pearson was hurt at work and received an award for back and knee injuries.[434] The facts show that the worker had injured his knee five years earlier and was diagnosed with significant pain in his right knee the year before the accident, with similar complaints after the accident.[435] While there was a causal link between the knee complaints and the accident, he had reached maximum medical improvement.[436] Therefore, the aggravation of his preexisting knee problem was not persuasively established as being permanent. Nevertheless, the Workers Compensation Court ordered the defendant to pay future medical expenses.[437]

Following this determination, Pearson had continued problems with his knee and underwent a total knee replacement.[438] He then sought to modify the original award and asserted that the TKA caused a "material and substantial change in his physical condition."[439] Following an appeal of his denial of additional benefits, the court found worker's compensation did not cover the knee replacement surgery.[440] Relying upon the opinions of two physicians, the court determined that the claimant's knee injury was only an exacerbation of a preexisting condition, and the TKA was not persuasively established as being related to the accident.[441] In fact, the claimant had developed symptoms in the opposite knee that were identical to the symptoms in the right knee he injured in the incident.[442]

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[431] *Id*.
[432] *Id.* at *5.
[433] *See* Pearson v. Archer-Daniels-Midland Milling Co., 828 N.W.2d 154, 162-63 (Neb. 2013).
[434] *Id*. at 157.
[435] *Id*.
[436] *Id*.
[437] *Id*.
[438] *Pearson,* 828 N.W.2d at 158..
[439] *Id*.
[440] *Id*.
[441] *Id*.
[442] *Id*. at 160.

V. SOCIAL SECURITY DISABILITY

Social Security Disability Insurance (SSDI) is a federal program whereby workers obtain benefits in a time of need by paying Social Security taxes on their wages. Disabled parties and their dependents receive assistance if the insured individual is unable to work for a specified period.[443] Disability is a word of art that refers to a person who is unable to engage in gainful employment because of a severe medical condition that "has lasted, or is expected to last, at least one year or results in death."[444] That medical condition must preclude the worker from engaging in tasks that they previously did, and it must bar them from accepting modified job responsibilities.[445]

Benefit eligibility is based upon a listing of impairments outlined in the Blue Book.[446] This guide lists specific measurements and symptoms that must be present.[447] Knee replacement surgery is examined in Section 1.00 – Musculoskeletal System and is listed as a "major weight-bearing joint.[448] This section provides that a person may qualify for benefits if they present medical evidence that either:

> You have a major joint dysfunction that includes anatomical deformity and chronic joint pain, stiffness, and limitation of motion that affects your knee and severely interferes with your ability to walk, [or] You have had reconstructive surgery or surgery on your knee because of your severe inability to walk, and you are not expected to return to normal movement for at least 12 months after surgery.[449]

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[443] SOC. SEC. ADMIN., *Facts*, https://www.ssa.gov/disabilityfacts/facts.html#:~:text=Social%20Security%20Disability%20Insurance%20(SSDI,workers%20and%20to%20their%20dependents (last visited Nov.15, 2022).
[444] *Id*.
[445] *Id*.
[446] DISABILITY BENEFITS HELP, *Medical Criteria Needed to Qualify with Knee Replacement*, https://www.disability-benefits-help.org/resources/medical-evidence/knee-replacement (last visited Nov. 15, 2022).
[447] *Id*.
[448] DISABILITY BENEFITS CTR., *Knee Replacement and Social Security Disability*, https://www.disabilitybenefitscenter.org/disabling-conditions/knee-replacement#:~:text=In%20knee%20replacements%2C%20metal%20and,knees%20are%20replaced%20at%20once(last visited Nov. 15, 2022).
[449] *Id*.

Section 1.17 is another section of the Blue Book that comes into play. This clause is entitled "Reconstructive Surgery or Surgical Arthrodesis of a Major Weight-Bearing Joint." It provides for a finding of disability if the applicant has had reconstructive surgery to the knee, the impairment has lasted or will last for more than 12 months, and there is a documented need for a walker, cane, crutches, or a wheeled and seated mobility device requiring the use of both hands.[450]

Over the years, knee replacement surgery has become a refined art with few complications and excellent results. As noted by the American Academy of Orthopedic Surgeons, 90% of knee replacement patients achieve significant pain relief.[451] In fact, 82% of knee replacements are still in use 25 years after their implantation.[452] These statistics are not lost upon those who adjudicate Social Security claims involving knee replacement surgery. A review of Social Security disability cases demonstrates that judges are not predisposed to award benefits merely because a person has had replacement surgery, even if it involves both knees. Instead, they want to see a person whose life's activities have been severely curtained as the result of the surgery with a continued narrative of pain and inability to function. Multiple instances can be found where the factfinder has discounted the claimant's testimony of continued knee complaints and limitations following surgical interventions. The following is a representative sample of cases.

In *Fletcher-Silvas v. Saul*, the claimant had bilateral knee replacements.[453] Although she had not fully recovered, her application for disability benefits was denied.[454] Her medical records demonstrated good progress, and her pain level was three or four out of ten, with an improved range of motion. She admitted that she engaged in regular physical activities even though they produced pain.[455] The claimant demonstrated no complications from her surgery, and her discomfort fell short of being disabling.[456] The appellate court upheld these findings because there was clear and convincing evidence to discredit her testimony about the severity of her symptoms.[457] The plaintiff claimed that her left leg only had slight

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[450] SOC. SEC. ADMIN., *1.17 Reconstructive Surgery or Surgical Arthrodesis Of A Major Weight-Bearing Joint*, https://www.ssa.gov/disability/professionals/bluebook/1.00-Musculoskeletal-Adult.htm#1_17 (last visited Apr. 18, 2023).

[451] Samuel Greengard, *Clinical Outcomes and Statistics of Knee Replacement,* HEALTHLINE *(*Apr. 15, 2020), https://www.healthline.com/health/total-knee-replacement-surgery/outcomes-statistics-success-rate (Hereinafter *Clinical Outcomes and Statistics of Knee Replacement*).

[452] *Id*.

[453] Fletcher-Silvas v. Saul, 791 F. App'x 647, 647-48 (9th Cir. 2019).

[454] *Id*. at 648.

[455] *Id*. at 649.

[456] *Id*.

[457] *Id*.

improvement, and her right leg was no better after surgery.[458] However, this testimony conflicted with the self-reports to her physicians about continued improvement in range of motion, strength, mobility, and gait mechanics.[459] She also failed to engage in self-help remedies such as losing weight and seeing a nutritionist.[460]

A similar result was demonstrated in *Pyles v. Astrue*.[461] The claimant had a severe impairment following surgery to the cruciate ligaments, which was followed by a right knee replacement.[462] However, the ALJ did not believe these issues satisfied the requirements of impairment for disability under the law.[463] The claimant had the functional capacity to sit for six hours and stand or walk for two hours in an eight-hour workday.[464] This finding was appealed but to no avail.[465] The court defined a disability under the Social Security Act "as an inability to engage in any substantial gainful activity by reason of any medically demonstrated physical or medical impairment which can be expected to result in death or which has lasted or can last for a continuous period of not less than twelve months."[466] To be declared disabled, the applicant must demonstrate an impairment that is so severe that the person is not only unable to perform his previous job "but cannot, considering his age, education, and work experience, engage in any other kind of substantial gainful work which exists in the national economy."[467]

The facts demonstrate that Pyles had his cruciate ligaments and medial meniscus surgically repaired. Several months later, most of his knee motion had been restored, but some instability was present.[468] Two years later, a total knee replacement was performed, and within a few months, the surgeon's records indicated that the patient had reasonable pain control and functioning.[469] While some pain was present, the surgeon told him to work through it.[470]

At the time of the administrative hearing, Pyles was 47 and trained as a cement finisher. He testified that he was still recovering from his TKA,

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[458] *Fletcher-Silvas*, 791 F. App'x at 649.
[459] *Id*.
[460] *Id*.
[461] *See* Pyles v. Astrue, No. 5:08cv344/RS–MD., 2009 WL 5171765, at *7 (N.D. Fla. Dec. 21, 2009).
[462] *Id.* at *3-4.
[463] *Id*. *at* *4, *7.
[464] *Id*.
[465] *Id*. at *2.
[466] *Id*.
[467] 42 U.S.C. § 423(d)(2)(A).
[468] *Pyles,* 2009 WL 5171765, at *4.
[469] *Id*.
[470] *Id*.

could not stand for more than 30 minutes, and could only ambulate for 40 to 50 feet.[471] The court was unimpressed with this narrative and upheld the denial of benefits. It cited the ALJ's findings that pointed to the treating doctor's notes, which indicated that Pyle could get on and off the examining table without a problem and that he should be able to return to work in six months.[472] The patient's range of motion was reported as "good," and his pain was under control.[473] While the claimant may have had some continuing knee issues, he was not disabled for twelve months.[474]

An administrative law judge's denial of benefits was reversed in *Wilson v. Commissioner of Social Security.*[475] Wilson suffered a severe leg injury in a motorcycle accident. He had not engaged in any substantial gainful employment since that time.[476] He needed crutches and braces to bear weight on his leg, and the doctor noted that the plaintiff had "suffered a complete destruction of his left knee."[477] Two years later, Wilson underwent a TKA, but his problems continued.[478] The court on appeal was dismissive of the ALJ's findings, which relied upon the reports of consultative examiners. The trial judge characterized one expert as saying that the claimant could return to "full" weight-bearing status.[479] In reality, the expert noted that Wilson could "bear weight without the use of an ambulation aid."[480] In the following sentence, however, the expert was "not able to state when the plaintiff was expected to "return to full weight bearing."[481] Also, the x-ray report relied upon by the defendant did not state that the fracture was "healed and solid" as reported. Rather, the surgeon noted that during the operation, he visualized the knee joint, and observed "some fibrous union but no solid union of the fracture."[482] Based upon the totality of the evidence, the ALJ should have concluded that the objective medical evidence supported the claimed disability for a lower extremity injury.[483]

CONCLUSION

[471] *Id*.
[472] *Id*.
[473] *Pyles,* 2009 WL 5171765, at *6
[474] *Id*. at *7.
[475] Wilson v. Comm'r of Soc. Sec., No. 00–10285–BC, 2002 WL 1608245, at *3 (E.D. Mich. July 16, 2002).
[476] *Id*. at *1.
[477] *Id*. at *2.
[478] *Id*.
[479] *Id*.
[480] *Wilson*, 2002 WL 1608245, at *2..
[481] *Id*.
[482] *Id.*
[483] *Id*.

Knee replacement surgery is one of the most frequently performed arthroplasty.[484] Its purpose is to resurface a damaged knee joint.[485] This intervention is a last resort for most people. However, surgery should be suggested only after all conservative treatment has been exhausted.[486] The goal of this intervention is to replace the eroded surfaces of the joint with replica parts.[487] The patient may undergo a total or partial knee replacement depending upon the severity of the joint's deterioration. While the implant is crafted to last fifteen to twenty years, any number of problems may arise, causing the device to fail prematurely.[488] Revision surgery is more complex, and the replacement prosthetic has a shorter life than the original implant. [489]

Knee implant manufacturers and surgeons can employ the utmost care in their craft. However, patient dissatisfaction still occurs with some frequency.[490] Infections develop, prosthetics loosen or prematurely wear out, and the device may be subject to a recall. Regardless of the reason for the patient's unhappiness, litigation is always a possibility, with causes of action sounding in negligence, product liability, and breach of warranty. Knee replacement claims also arise in disability, worker's compensation, and personal injury contexts. Billions of dollars have been paid to settle claims, so counsel needs to understand the medical and legal implications of this type of litigation. It is hoped that this article provides counsel with that type of primer for handling or defending TKA claims.

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[484] *2021 Annual Report*, *supra* note 3.
[485] *Knee Replacement Surgery Procedure*, *supra* note 14.
[486] *How Is It Performed, supra* note 105.
[487] *Id*.
[488] *Lum*, *supra* note 148.
[489] *Harris-Ray*, *supra* note 180.
[490] *Greengard*, *supra* note 125.