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Litigation and access to healthcare: an analysis of universal coverage and judges' decision making criteria

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Abstract

Public insurers face trade-offs between the individual and collective benefits they can provide given limited resources. Drug expenditure is one of the largest components of health spending and it is not clear cut what should be readily available. We study litigation as a safety valve using data from cancer drug requests filed in court in Costa Rica, a country with a universal healthcare system. As a standard, decisions on rationing are based on economic evaluations of health care, but a probit model to predict lawsuit success shows that higher benefit drugs do not have higher success probabilities even if this would be the desired outcome from the individual's perspective. Marginal costs, which approximate cost-benefit ratios, do show a significant effect but of a smaller magnitude, making the Court differ from the public insurer's rationing rule. Regarding social determinants of health, variables such as education, income and region don't appear to generate a bias from judges. Moreover, as prevalence and mortality are commonly used to characterize diseases and their severity, we examine the types of cancers involved in litigation and assess whether healthcare coverage explains any patterns. Overall, no clear patterns emerge, indicating that the Court's role in drug access complements the population-level rationing rules, addressing individual heterogeneity. For judges, the findings do not suggest a cautious approach for prevalent diseases, but they do place a high value on the probability of survival. So far this last factor appears the most relevant for Court rulings. Finally, an event study model shows that no drug or diagnosis guarantees lawsuit success, and past decisions do not significantly influence future ones, which is a common concern according to public opinion. This research sheds light on the complex decision-making process regarding drug access under a universal healthcare system and highlights the importance of balancing individual and collective well-being in resource allocation.

Keywords: litigation, healthcare, drug-access, cost-effectiveness, prevalence, mortality.
JEL Codes: D61, D71, H40, I11, I13, K41

1. Introduction

Given resources are limited, rationing is inevitable in any type of healthcare system. Public insurers (PI) face the particular challenge of balancing individual and collective welfare (Hauck et al., 2019; Schut and Van de Ven, 2005; Verguet et al., 2016) when allocating their available resources. Thus, they require a set of rules (Bryan et al., 2007), and these are typically based on some form of economic evaluation (Neumann et al., 2015).

While rationing rules ensure that a PI maximizes public value from their limited resources, individuals seek to maximize the private value they get from healthcare; thus, if they expect a higher value to come from obtaining the service not provided, they will be motivated to get around the rules set by the PI. For example, individuals might travel to another country where they can obtain the health service that wasn't available to them (Flood and Gross, 2014).

These methods to get around rationing rules can be seen as safety valves for a health system. Given the heterogeneity in expected outcomes from health services, it is rational to expect that there exist outliers among the population for whom a particular health service deemed not covered due to cost or benefits is reasonable. The most common safety valve in healthcare systems is litigation (Flood and Gross, 2014). Individuals sue the insurer in order to gain coverage that had been denied (Vargas-Peláez et al., 2014).

While there is a general understating of how decisions in healthcare are made by an individual (preferences), a provider, and a public insurer (economic evaluations), there isn't one about what happens when litigation gets involved. The judicial system receiving a plaintiff's complaint against a public insurer is faced with the following situation. Assuming the PI's

rules are obtaining the most value for the population they serve, reallocating resources for an individual will cause harm to the public. However, given the heterogeneity of outcomes, the plaintiff's claim could be reasonable in terms of the value it is expected to yield.

The outcome of this type of litigation is relevant for social planning (Jung et al., 2014), and this creates a need to understand how these decisions are being reached. In an effort to shed light into the decision-making mechanisms behind litigation when used as a safety valve from rationing rules, we study oncology drug requests using litigation within the Costa Rican public healthcare system.

This setting is particularly compelling for two main reasons. First, spending on drugs is one of the largest components of healthcare expenses worldwide (Tomic et al., 2018). Second, cancer is a leading cause of death around the world, and there has been a shift away from conventional cytotoxic drugs causing a substantial rise in the cost of cancer treatments while offering at best modest benefits (Etzioni et al., 2015). Thus, cancer treatments are a key component of overall healthcare costs (Wallace, 2013).

Further, Costa Rica has a publicly funded universal health care system with extensive coverage throughout the country. It has achieved health outcomes that are often considered to be on par to those of developed nations (Rodriguez Loaiza et al., 2018). Litigation on constitutional matters such as the right to health has been designed to have very low barriers to access. As a result, litigation as a safety valve for the healthcare system's rationing has gained prominence, with annual cases steadily increasing (Programa Estado de la Nacion, 2017) and drawing more attention from the general public and health authorities (Norheim and Wilson, 2014). It is important to note that when the public insurer is sued, the court's decision will only provide access to the drug for the individual. Anyone else seeking to get the same drug would have to sue as well.

Overall, there is limited evidence on litigation as a safety valve for healthcare access. Most studies are anecdotal and descriptive; they draw mixed conclusions in terms of the outcomes from litigation and criteria for rationing. In terms of empirical evidence, the data set constructed for this paper is unique in its ability to provide evidence not just on the cases themselves, but also in that it merges in clinical data on the diagnoses and treatments, their costs, the public burden of these diseases, and judge identity.

The main goal is to determine what factors predict litigation success regarding access to drugs. This is relevant to how we think of access to healthcare, as well as to how we understand the collective effect of litigation as a safety valve. Even if the first order impact is individual, second order effects arise from the stress placed on public funds in the case of successful litigation, forcing the insurer to meet the individual's request.

We use probit models to predict the probability of successful litigation - defined as when the court approves a drug request and the insurer has to provide said drug, henceforth referred to as approval probability.

First, we ask whether judges are using expected benefits (hypothetically the main driver of individuals) to determine approval. We find that higher benefit drugs have a higher likelihood of approval. Then, we add economic criteria (similar to the PI's rationing rules) into the model and find that while the benefit-cost ratio has no effect, costs have a large positive effect on the likelihood of approval. This suggests that judges could be assigning value to expected outcomes from individuals, and shows no evidence that they consider social planning.

Second, we consider whether the prevalence and mortality of a disease bare any relevance in these litigation cases. Prevalence and mortality change how a diagnosis is perceived outside of the healthcare field. Thus, it is reasonable to expect them to affect a judge's decision, but their effects on approval probability are unclear. In theory, higher mortality is likely to induce sympathy and increase approval probability, while higher prevalence is likely to induce caution due to a larger pool of similar patients that could sue as well.

Results don't indicate a trend where diagnosis type (prevalent or lethal cancers) drives court cases. This may support the idea that the Costa Rican healthcare system is fulfilling the goal of expansive coverage. As for the Court as a mechanism to access treatments, it may indicate the Court responds to heterogeneity in individual cases. This addresses demand unmet due to system wide cost-effectiveness rules.

Prevalence as a predictor of approval probability does not appear to be a significant factor. As for mortality, survival is highly valued by judges. Higher mortality, lowers the likelihood of approval. With higher mortality, there are higher incremental cost benefit ratios and the Court may focus more on chance of survival rather than on costs.

Finally, we look into the trend of litigation over time with an event study model. We check whether legal precedent predicts approval by reviewing auto correlation over time, and do not find that past decisions are related to future ones.

2. Background

2.1. Economic evaluations in healthcare

Factors influencing the guidelines for decisions in healthcare are not limited to cost-effectiveness and decisions can depend strongly on decision-maker preferences (Eichler et al., 2004). Cost-effectiveness, individual health benefit and severity of disease, have

been found to be all significant and equally important determinants to recommend health interventions (Baji et al., 2016). Still, there is evidence that important differences arise in the weight given to efficiency and equity attributes (Baji et al., 2016). Further, equity-efficiency trade-offs in cost-utility analysis have shown a preference for the equality observed in the allocation of healthcare (Bleichrodt et al., 2005).

In public healthcare systems patients can choose to address their demand elsewhere. A study on restrictions based on cost-effectiveness and wait lists shows the choice of opting out depends on income and observes re-distributive effects and benefits for relatively rich individuals (Levaggi and Levaggi, 2017). Other analyses look into implicit rationing in health care and the factors influencing these decisions of opting out or not seeking coverage. These find income to be the most relevant factor (Salvucci, 2014).

A wide range of articles discuss the use of cost-effectiveness analysis in healthcare resource allocation and explore how efficiency measurements have been used to support decisions in a variety of systems (Bryan et al., 2007; Cylus et al., 2016; Eichler et al., 2004; Verguet et al., 2016). These indicate the need of cost-effectiveness thresholds and the existence of a poor alignment between health maximization objectives assumed in economic analyses and a range of other objectives that decision-makers are facing. However, these are qualitative studies on rationing and often limited by data availability for identification. Another set of studies documents evidence from different settings, such as in Norway and Germany, but there is no consensus as to how to balance cost-effectiveness and fairness (Oduncu, 2012; Bridges et al., 2010; Ottersen et al., 2016).

When it comes to litigation as a safety valve, it is most common in systems with less flexibility in their thresholds for rationing. Anecdotal and comparative analyses show that having health as a right gives way for litigation to have a more prominent role (Flood and Gross, 2014; Boumil and Curfman, 2013).

Evidence about what litigation does to a universal healthcare system is mixed, some studies find that it expands inequities and weakens the system (Biehl et al., 2012). Other studies argue that by closing the coverage gap for the litigants is enough to make it worth it (Brinks and Gauri, 2014). The main issue with these studies arises from data limitations, they fail to account for geographical variation in populations and access to health services and lack health outcome measures (Biehl et al., 2012; Rosenbaum, 2000).

Regardless, in public insurance healthcare systems there has been a significant increase in litigation for access to services with a primary emphasis on drugs (Abramovich et al., 2008; Nunes, 2010; Avila Machado et al., 2011; Gable and Meier, 2013; Da Silva and Terrazas, 2011).

2.2. Considerations on trends of costs of health care and litigation

Literature in public policy showcases several case studies that propose improvement in well-being through litigation when seen from an individual perspective. Identification of trends in litigation and characterization of court cases propose this to be a tool for government accountability and a mechanism of self-selection that can account for individual heterogeneity in benefits (Da Silva and Terrazas, 2011; Biehl et al., 2016; Rosenbaum, 2000).

In terms of cost-effectiveness analysis in health care, several articles have explored its application in matters of allocation and rationing without a clear consensus of the fairness of the mechanism (Oduncu, 2012; Ottersen et al., 2016; Bryan et al., 2007; Cylus et al., 2016; Eichler et al., 2004; Verguet et al., 2016).

In public healthcare systems, the current trend has been a significant increase in prices of medications. This leads to a scenario where litigation is also bound to increase, with an emphasis on access to drugs (Abramovich et al., 2008; Gable and Meier, 2013; Avila Machado et al., 2011; Da Silva and Terrazas, 2011).

To further talk about caution, ICERs (incremental cost-benefit ratios) have a role in the evaluation of medical interventions and can speak to the influence of rationing considerations in litigation. Economics and law literature, both in cases for the right to health, as well as in other subjects, have not shown evidence that economic concepts such as effectiveness are effectively used in judicial rulings, despite its direct link to an economic framework (Clarke and Kozinski, 2019).

Though anecdotal and limited, evidence from the Costa Rican system shows that approval of access to certain treatments by the court has lead to higher rates of litigation and a greater strain on the system. Hence, an important question is how cautionary should judges be in granting access to previously rationed services. Event study models have their limitations but have had an important role in policy analysis and help assess the pattern of requests (Freyaldenhoven et al., 2019; Dobkin et al., 2018).

2.3. Healthcare system in Costa Rica

Costa Rica possesses a universal health care system with a tax-funded, single-payer structure that offers a comprehensive package of services free at point-of-use. The public insurer in charge of the country's public health sector is an autonomous centralized institution established since 1941 called the Costa Rican Social Security Institution (CCSS) (from hereon referred

to as the *public insurer*). The public insurer (PI) has the role of policy maker from the design to implementation and oversight of health services.

In the matter of drug coverage, system-wide regulations for pharmaceutical products are established by the public insurer via a Central Pharmacotherapy Committee. Drug coverage is managed through an official formulary known as the *Official Pharmaceuticals List*. To put together this list of medications, an ordinance establishes that that they follow cost-effectiveness analyses as their main inclusion criteria (Comite Central Farmacoterapia, 2019). Unfortunately, specific data used in this decision process is not public. Drugs are listed by active principle (molecule)[1] and all approved indications, presentations and strengths.

If a doctor wishes to prescribe one of these informulary drugs for a non-listed indication, presentation or strength, they may do so using some additional paperwork which evidences the potential benefit. This process is not excessively burdensome and resolved favorably and quickly in the vast majority of cases by local health services administrators. All drugs in the formulary are covered, which means they will be provided at no cost across the entire provider network.

If the provider considers a treatment outside of the formulary is appropriate, they can make an internal request to the Central Pharmacology Committee. The patient has no agency in this process with the PI having all the decision power. This process is quite burdensome for the doctor, requiring extensive paperwork and attending hearings and may involve additional testing and evaluations for the patient. Additionally, the PI does not disclose any data on these requests.

2.4. Judicial system in Costa Rica

The supreme court of the country was established in 1825 and was divided into three 'chambers' who possess a specific prerogative on which cases they address. In 1989, a fourth division is established with the sole jurisdiction over matters that relate to any infringement of rights protected by the Constitution of 1949. This is the "Constitutional Chamber". The accessibility of this chamber is guaranteed for all individuals. This is achieved as it has no monetary barriers attached to its use, no need for formal legal representation, enforcing strict maximum deliberation periods, rulings are strictly enforced and six month follow up periods are stipulated (Programa Estado de la Nacion, 2017).

The Constitution endorses the United Nation's Declaration of Human rights, hence protecting the human right to life. This is further interpreted by the judiciary power as the right to health (Programa Estado de la Nacion, 2017). It follows that the state should be ensuring a minimum standard of health and this provision is through the public insurer. By this rationale, drug access requests through litigation have become cases of 'constitutional' rights. This right is exercised by presenting a claim to the court in the cases where there is belief that the failure of the system to provide a drug for a given diagnosis constitutes a violation of the individual's right to health. If this happens, there can be two types of cases depending on what they believe and the drug involved. First, a case where they in fact meet the criteria for readily available medications. Second, a case where their condition in fact requires a medication not included in the list at all.

For the claims, there is no requirement to provide evidence themselves other than their personal information and the drug requested. Once the appeal is presented, a panel of 7 judges makes a decision (by a vote and simple majority) on whether to approve or deny the motion. If approved, the public insurer has the obligation of complying with this decision (without any further chance of appeal) and will do so within a specific time frame also determined by the court once they make a ruling. Prior to deliberation, the court reaches out to the public insurer in order for them to submit evidence in their defense. If the decision is to approve the drug request, then a time frame for compliance is also determined.

Both the healthcare system and the litigation system are well established and citizens are widely familiar with both. It is important to note that if a patient is not satisfied with the drug provided by the public insurer, their only recourse is to use the Court or obtain the product by their own means. However, with this last option there are two key considerations.

First, costs for the patient. Second, some drugs (most cancer treatments) are not available in private pharmacies. Over 90% of the population is covered by the PI. The private healthcare sector is small and mostly focused on simple or straightforward interventions. Chronic, complex or specialized interventions are typically referred to the public insurer. Thus, private providers have no incentive to have specialized, and/or expensive drugs available for purchase. Additionally, privately acquired drugs cannot be administered by the public insurer's personnel, so drugs that require any monitoring or hospitalization for their use would have the added cost from these types of private services.

In this context, the Court has emerged as a mechanism to access drugs bypassing rationing rules determined by the public insurer. However, judging if drug requests are reasonable or not is complex. From a clinical perspective, if the request increases expected benefits while outweighing the risks, it is reasonable

[1] By law, as a cost control mechanism, if a generic version of the drug is available it must be the prescriber and pharmacist's first choice.

for a patient to demand the treatment. From a policy perspective, a request that improves efficiency in the allocation of resources would be considered reasonable.

These perspectives are not necessarily contradicting as they likely overlap in most cases. However, this depends greatly on how benefits, risks, and efficacy are measured. The available evidence in support of these measurements varies widely, from reliable to unreliable, peer-reviewed to single case reports, or something in between.

Measurements evaluating treatments are determined based on the disease being treated, so characterizing the types of diseases using the Court to gain access to drugs is vital in understanding the functioning of the mechanism.

Among the most standard indicators to characterize a disease are prevalence and mortality. These epidemiological measures are extensively used in medicine (Wunsch and Gourbin, 2018). In a clinical setting they are necessary inputs to understand a disease's behavior and give context to treatment options for both doctors and patients. In a policy setting these are vital indicators used in planning resource allocation for healthcare.

3. Theoretical framework

3.1. Cost-effectiveness and rationing

The process of implementing rationing rules to determine drug coverage by a public insurer (PI) is institution-specific, but at its core there is a measure of expected benefits and costs. In Figure 1, the y-axis shows the expected benefits and the x-axis the costs of covering a drug for the PI. The PI sets a cost-effectiveness threshold (PI threshold) to decide which drugs are covered (shaded area above the threshold) and which are not (non-shaded area below the threshold).

In Panel A, the health care system only has PI rationing rules to determine drug access. Drug A is covered and provided at no cost to an individual, whereas drug B is not. The costs of the drug do not vary across individuals but the expected benefits do. This distribution of benefits is indicated by the bars. With individual heterogeneity, some individuals expect to receive more benefits than the average user, and some are expected to receive less.

For patients whose actual expected benefits from B are above average (triangle in upper bound of measurement error), they would pass the PI's rule for covering drugs. However, the decision for drug B is made based on average measurements and hence they are denied coverage. If litigation for drug access works by allowing these individuals to obtain the drugs, then we expect to ameliorate inefficiencies due to individual heterogeneity.

This scenario is in Panel B, where the court deciding on litigation requests approves cases for which benefits and costs place the drug in the area just above and below the PI's threshold (light shading). Cases for drug B with benefits in the upper-bound (triangle) are approved and the PI must cover the drug, while cases with benefits at the lower-bound (square) are not approved so the PI doesn't have to cover the drug.

However, there is no evidence that this is how courts decide on access to drugs. An alternative is that the court has a lower threshold than the PI (Panel C). Another one, is that the court lacks cost-effectiveness, benefits or cost thresholds. In this case they would just consider individual cases and decide to approve them or not (Panel D). Here requests for B at the lower bound (square), C and D were approved, but a case for B at its average is rejected. In both of these alternatives (panels C and D) lower-benefit cases for drug B are approved by the court. These decisions do not match the public insurer's rules.

3.2. Role of prevalence and mortality

A guiding principle for the Costa Rican health care system is universality, interpreted not only as giving access to all, but giving sufficient access to all. In practice this means that no disease is considered too rare or too expensive to be managed and covered by the public insurer.

If this goal has been achieved, then one would expect that cases using the Court to access drugs show no pattern in terms of prevalence rates for the diagnoses involved. If rare diagnoses are found to be the main source of Court cases, this means patients with these diseases are not receiving adequate treatment. By law no diagnosis can be excluded from coverage, so this would mean that the treatment options covered do not meet patient's demands.

One possibility is that requests are mainly for orphan, experimental or recently innovated drugs. These drugs typically have high costs, and low benefits. Alternatively, benefits may not have substantial evidence. In these conditions, the public insurer would not include these drugs in the official formulary, forcing patients who want access to them to go to Court.

Similarly for mortality, the idea is that no pattern should be observed among court requests. Again, from the public insurer's perspective there is no reason for mortality to determine coverage. However, more lethal diseases could lead to patients demanding orphan, experimental or recent innovation drugs, which as stated previously should not necessarily be covered from a cost-effectiveness perspective.

We would not expect a pattern from common (or rare) diseases or lethal (or non-lethal) diseases mainly contributing to Court cases, given Costa Rica's good health outcomes overall (Norheim and Wilson, 2019).

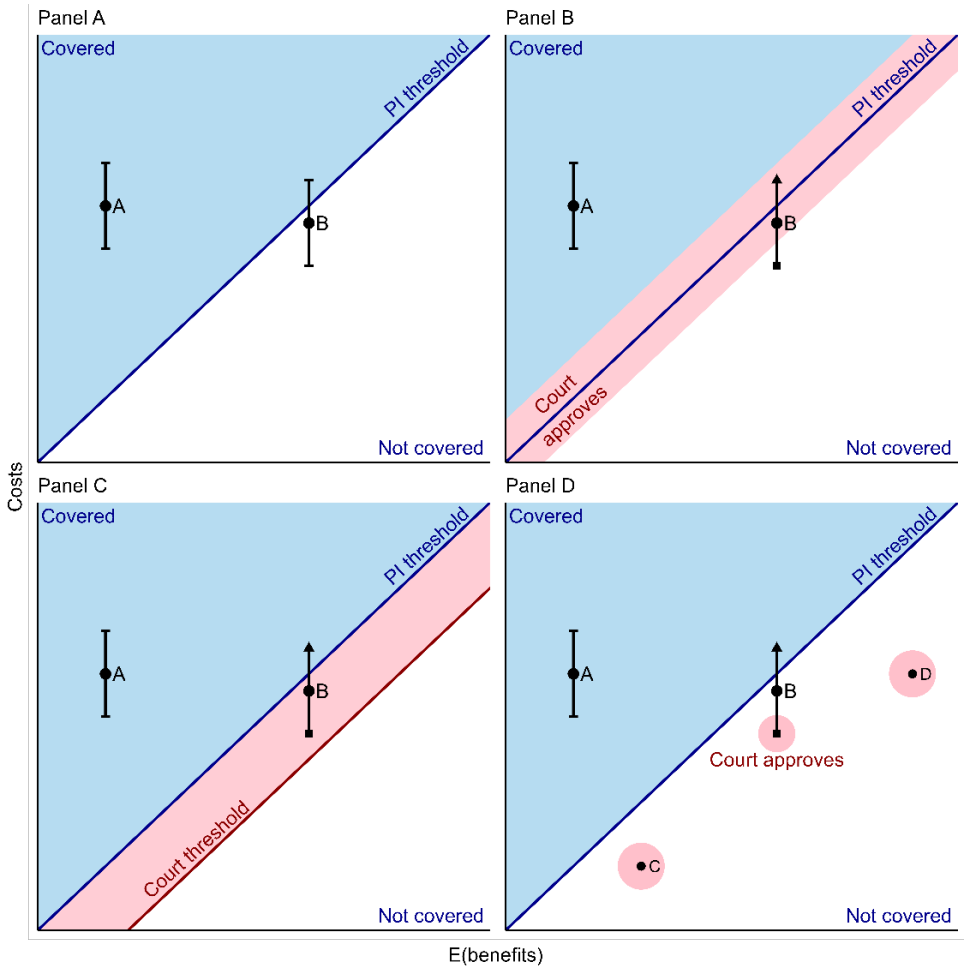

Figure 1: Conceptual model for litigation's role in drug access

Notes: E(benefits) refers to expected benefits. PI refers to public insurer. Covered drugs (dark shading) means cost-effectiveness is sufficient so the PI provides them at no cost. Not covered (no shading) means cost-effectiveness is insufficient so the PI doesn't provide the drug. Court approves (light shading) represents possible cost-effectiveness values for which the Court approves requests. In Panel A access to drugs is solely regulated by the PI's rationing rule using cost-effectiveness to set a threshold. In Panel B access to drugs is possible via litigation and the Court focuses on drug benefit heterogeneity around the PI threshold. In Panel C the Court decides using a cost-effectiveness threshold of their own. In Panel D the Court decides based on individual cases.

If this were observed, the hypothesis is that the group self-selecting to go to Court is significantly different from the overall population.

Continuing with how prevalence and mortality could influence judges' decisions, in theory there are 2 mechanisms. First, rare diagnoses means that there are fewer potential patients, whereas common diagnoses mean that there are more potential patients to go to court in the future. Judges might be more reluctant to approve a request for a common disease, especially high-cost requests, as they see more potential patients and hence future cases. Whereas they might be less cautious if the disease is rare.

Additionally, judges are less likely to have any knowledge of rare diseases, so their ability to determine a treatment's effectiveness may be more limited. The opposite is true for common diseases.

Lethal diseases are likely to induce sympathy in judges which would increase the likelihood that their requests are approved regardless of benefits or costs. For non-lethal diseases, sympathy would not play a factor and the approval probability is likely to be lower, especially for high-cost or low-benefit drugs.

Further, independent of judges' perceptions, mortality and prevalence changes the benefits and costs expected from drug requests. Due to low survival probabilities for more lethal cancers, expected benefits from treatment will be lower than for less lethal cancers.

With rare diseases, these are more likely to have less treatment options, and these are more likely to be high-cost with less expected benefits (or unproven) (Pavlidis et al.). This suggests that there will be increased expected costs from rare disease treatment re-

quests than for common diseases.

These possible effects are shown in Figure 2. The x-axis is mortality; the y-axis is prevalence. Each quadrant shows an intersection between mortality and prevalence, with the corresponding prediction regarding approval of a request, and the resulting incremental cost-benefits ratio (ICBR) of the requested treatment.

Rare cancers are expected to have high approval probabilities and ICBRs when compared to common cancers, due to judges being less cautious and costs likely to be higher. Within the rare cancers, more lethal ones (lower right quadrant) are expected to have higher approval probabilities and ICBRs than non-lethal ones (lower left quadrant), due to inducing sympathy in judges and having less chances of survival regardless of treatment.

Among common cancers, non-lethal ones (upper left quadrant) are expected to have lower approval probability and ICBRs due to less sympathy and less expected benefits when compared to more lethal cancers (upper right quadrant).

4. Data

4.1. Court rulings and initial data extraction process

In order to address these questions a novel data set is used for court decisions on drug request cases. Court rulings are recorded in the Costa Rican Judicial Information System for the whole country. Rulings are stored as documents in consisting of three parts: (1) request filed by the injured party, (2) summary of the defense's evidence, and (3) the court's decision.

First, the requested drug is identified, and it is determined if it is a generic drug. Next, diagnosis and medical specialty are associated to each case. Other variables extracted include filing date, ruling date (variables from which deliberation time in days is calculated), the number of documents submitted as evidence by the public insurer (as a proxy for strength of the defense), the appeal status (if the case is an appeal of a previous court decision), and the resolution (approval or not of the drug request). Furthermore, variables relating to socioeconomic background, education, income and region are extracted for each case.

4.2. Data on judge panels

A second revision of the documents takes place to extract judge characteristics and specifics on how they ruled in each case. Since the documents are filed under a specific number sequence it is possible to match the cases and merge the new data extracted with the original dataset.

The court summarizes the details on the request, the evidence being presented and the court's decision yielding reports of approximately 10 pages. We review copies of the original reports collecting information on the judges. The 3,124 cases on drug requests from which information is manually collected have 6 judges per case with a presiding judge (president of the court and 7^{th} vote), one judge is redacting the report (in nearly all cases part of the 7 votes) and the judges that voted contrary to the final court ruling. These variables are logged as judge dummies (for a total of 55 judge dummies), a string variable for president, another one for redacting judge and 3 'saved' vote variables per case (when it was not unanimous) with string variables for the judge of each vote.

4.3. Drug formulary

Drug-diagnosis formularies are created for the entire healthcare system and determine the rationing and administration of these medications. These lists are based on cost-effectiveness analysis, public and have been published biannually from 1992 to 2014.

To determine drug coverage status for drugs in court cases, the data base uses the date on which the drug gained coverage and is then compared to the filing date of the case.

Nevertheless, since lists are by drug and diagnosis, often cases are not for uncovered drugs but because they are requesting an unapproved dosing or intervention according to the profile and diagnosis of the patient. If they do not meet the combination of the criteria the lists are establishing, then they can use litigation for access.

4.4. Costs and benefits

Most cancers have standards for diagnosis and treatment defined by internationally accepted guidelines and this allows benefits and costs at an individual patient level to be determined[2].

Thus, benefits are constructed with age, gender, diagnosis (type and stage of cancer [3]), treatment prior to litigation and if drug requested is symptomatic or for treatment. The guideline recommendations are then analyzed and expected benefits are measured using requested versus prescribed drugs in the form of months of progression-free survival. This clinical endpoint is defined as the time it takes for the cancer to progress after beginning treatment and is a measurement widely used in cancer research[4].

[2]The National Comprehensive Cancer Network's clinical practice guidelines are recommendations specific to individual-diagnosis-stage combinations that also explain peer-reviewed medical literature on which they are based.

[3]According to the Tumor-Node-Metastasis System of the International Union Against Cancer (scale from 1 to 4)

[4]Measure supported by the United States Food and Drug Administration (Food and Drug Administration, 2018)

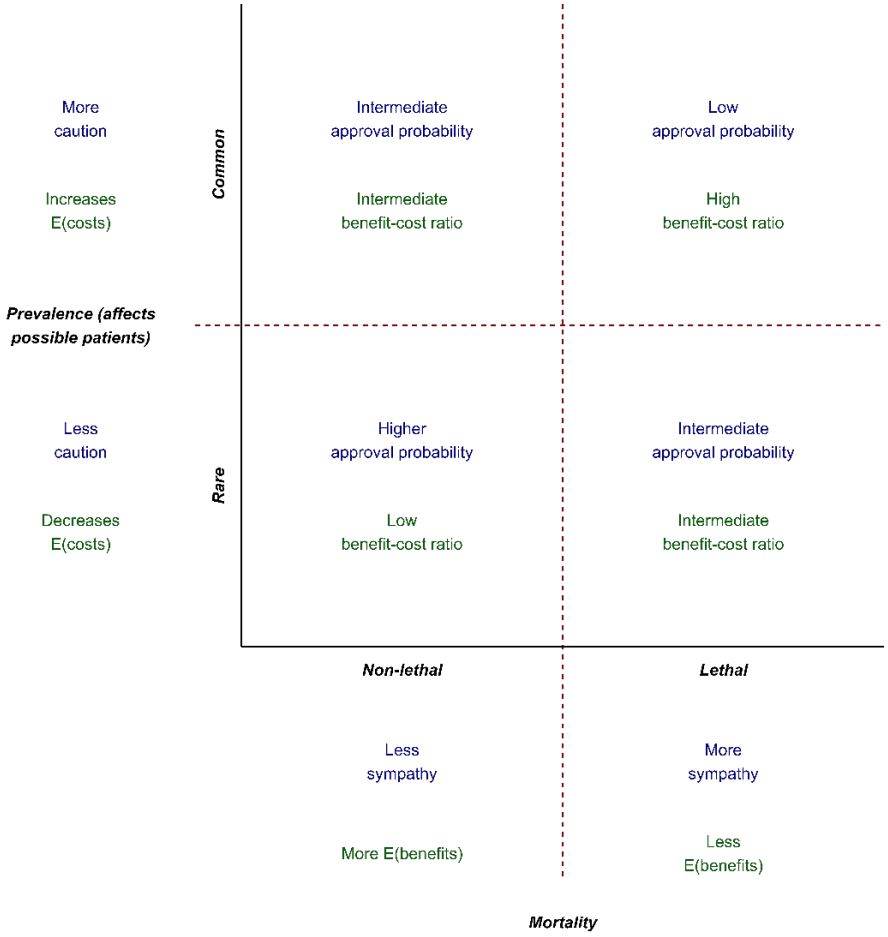

Figure 2: Hypothetical factors related to prevalence and mortality affecting judges' decisions and the resulting cost benefit ratios (ICBRs) from treatments

Notes: Incremental cost benefit ratios (ICBR) serve as a proxy measure of effectiveness. The numerator is incremental costs and the denominator incremental benefits. Prevalence is divided into rare (low prevalence) and common (high prevalence) cancers. Mortality is divided into non-lethal (low mortality) and lethal (high mortality) cancers. Notions of sympathy, perception of the likelihood of being cured, and caution due to the possible number of patients are hypotheses of how judges might feel regarding the probability of dying from a diagnosis and would impact the likelihood that a judge approves a request. Expected costs and benefits are interpreted from the judges' perspective (what they would expect in each scenario).

Also, the calculations of the benefits explained will differ from standard measurements of life expectancy from the pharmaceutical companies and will provide more insight on the functioning of the health care system and litigation as a safety valve.

As for costs, documents detail prices and dosage to be purchased by the public insurer. These are taken in 2017 US dollars. When treatment was not granted, then expected cost was estimated according to what would be the recommendation from the guideline. Having both benefits and costs, the ratio is straightforward and is used as benefits over costs.

4.5. Prevalence and mortality

Prevalence and mortality data for cancer diagnoses was obtained from the Costa Rican Health Ministry's Epidemiological Observatory. The data is recorded according to anatomical location which allowed for a precise match between the Ministry's diagnoses and those found in court cases.

The data consists of measures of prevalence and mortality specific to age group (for every 10 years), sex and cause from 2009 to 2015 for Costa Rica. In order to calculate rates, population data (with age and sex specific entries) was taken from the National Institute of Statistics.

Mortality rates were corroborated with the public insurer's National Tumor Registry which allows access to aggregated data on cancer mortality. Though the rates are informative, the measure shows the risk of dying from the diagnosis. These cause specific mortality values are converted into the probability of

dying within a five year period conditional on having said specific cancer.

4.6. Descriptive statistics

4.6.1. Statistics on all drug requests

For all the requests descriptive statistics are shown in Table 1. There are 3,124 requests, 663 different drugs, 290 of those drugs were requested only once, 307 different diagnoses and 26 different medical specialties.

The mean court approval is 0.55. Appeals made up 6% of cases. Mean deliberation time is 39 days, and by three and six months, 94.8% and 98.4% of cases were resolved. One quarter of requests were for drugs already covered and 37% of requests involve drugs that never gain coverage (at least until February 2019). Additionally, over half of the requests (53%) were for generic drugs (no brand was specified).

Among the ten most frequently requested drugs, 7 are for treating cancer and their approval probabilities range from 0.48 to 0.90. As for the diagnoses, they were all chronic diseases or cancers with approval probabilities of 0.30 to 0.82 (see Table 2).

4.6.2. Statistics on cancer drug requests

Descriptive statistics for cancer drug requests are in Table 3 with 1,236 requests, 161 distinct drugs and 65 of which were only requested once, and 51 different diagnoses.

Average court approval (for cancer requests) is 0.70. The percentage of appeals and average deliberation time are the same as for all requests. Mean individual age is 53 years old with 65% female individuals. On average, individuals had a cancer stage of 3.22 (and a median stage of 3). As this is an advanced stage for diagnosis, it would make since this is the average case going to court given the lower expected benefits and higher relative costs for this profile of patients.

The variables describing the requested drug characterize what type of request defendants are making. In contrast to the full data set, only 18% of cancer requests were drugs already covered.

Generic refers to requests that do not specify a drug brand. This is observed in 54% of cases, and these could be interpreted as more reasonable requests since branded drugs are bio-equivalent and do not produce different effects. However, requesting a brand would be reasonable if the reason for the specific brand is due to adverse effects from consuming the generic, or there is no generic version available.

Requests for the same molecule indicate that the patient's request is for a drug that is bio-equivalent to the current treatment being provided by the public insurer. This happens in 17% of cases and could be seen as unreasonable requests due to both drugs producing the same effects unless adverse effects are proven to occur with the current treatment.

Cases were the drugs requested are symptomatic occur in only 6% of cases. Symptomatic treatments, refers to treatments whose goal is to address symptoms and not the disease itself. Examples of symptomatic drugs include anti-emetic (to counter nausea and vomiting) medication and pain killers which do not treat the disease but are still necessary for cancer patients.

In almost half of the cases (44%), the requested treatment would replace the treatment currently being provided by the public insurer. This measure suggests that patients are receiving treatment, just not one that completely satisfies their demand.

4.6.3. Statistics on incremental costs and benefits

Regarding costs, the average for recommended treatments (taking duration and dosage) of requested drugs is 20,566 dollars, and for prescribed drugs it is 5,390. Incremental costs were defined as the cost of requested drugs minus the cost of prescribed drugs. The average was $63,323.83 with a maximum value of $166,790.81.

Average progression-free survival or benefits from requested drugs is 16 months, and from prescribed drugs 11 months. The average incremental benefits is 54.61 months, with a maximum value of 140 months. Similar to incremental costs, incremental benefits come from subtracting the benefits from using requested versus prescribed drugs.

Furthermore, we define marginal costs and benefits. Marginal benefits refers to the proportion of remaining expected life and have an average of 0.18 in the cases studied. Marginal cost refer to the cost in USD of gaining one additional year of life and have an average of $447,073.16.

4.6.4. Statistics on prevalence and mortality

The 41 diagnoses observed were grouped according to what anatomical system they involve and are presented in Table 4 along with several descriptive characteristics. The most observed diagnosis was breast cancer, which is reflected in the Female Reproductive System having the most cases.

For each diagnosis, conditional on having the disease, the rate per 1,000 people of Court cases was calculated. In column 2, the average rate for the diagnoses corresponding to the listed anatomical system is shown. For instance, for every 1,000 persons with a hematolymphatic system cancer (including lymphoma, multiple myeloma, leukemia, among others) over the six-year period, 6 persons filed a Court case requesting a drug.

The highest rates are found in cancers of the female reproductive system (11 cases filed for every

Table 1: Descriptive statistics for drug requests

No. of requests	3,124			
No. of drugs	663			
No. of drugs requested once	290			
No. of diagnoses	307			
No. of medical specialties	26			
Court decision process	*Mean*	*SD*	*Min*	*Max*
Approval	0.55	0.50	0	1
Appeals	0.06	0.23	0	1
Deliberation time (days)	39.94	41.63	0	350
Requested drug				
Covered[1]	0.25	0.44	0	1
Never becomes covered	0.37	0.48	0	1
Generic	0.53	0.50	0	1

[1] Drug covered by the Public Insurer's benefits package at the time the request was filed.
Source: primary hand-collected data for all drug requests in Costa Rica from 1991 to 2017.

Table 2: Approval probability for the most frequently observed drugs, diagnoses and medical specialties

	(1) Frequency	(2) Approval probability	(3) SD
Requested drug			
Anastrozole	185	0.48	0.50
Trastuzumab	120	0.89	0.31
Clopidogrel	82	0.35	0.48
Bevacizumab	76	0.74	0.44
Irbesartan	53	0.53	0.50
Sildenafil	50	0.44	0.50
Mercaptopurine	48	0.90	0.31
Abiraterone	44	0.77	0.42
Sorafenib	41	0.71	0.46
Sunitinib	41	0.78	0.42
Diagnosis			
Breast cancer	481	0.66	0.47
Epilepsy	131	0.50	0.50
Prostate cancer	115	0.67	0.47
Leukemia	108	0.82	0.38
Diabetes mellitus type 2	85	0.35	0.48
Hypertension	81	0.47	0.50
Colon cancer	74	0.72	0.45
Depression	60	0.30	0.46
Ischemic cardiopathy	60	0.38	0.49
Kidney cancer	57	0.75	0.43
Rheumatoid arthritis	57	0.63	0.49
Medical Specialty			
Oncology	1,236	0.70	0.46
Neurology	326	0.50	0.50
Cardiology	291	0.51	0.50
Psychiatry	232	0.32	0.47
Gastroenterology	210	0.60	0.49
Endocrinology	120	0.46	0.50
Rheumatology	114	0.51	0.50
Pulmonology	72	0.58	0.50
Urology	67	0.34	0.48
Infectology	52	0.44	0.50

Source: primary hand-collected data for all drug requests in Costa Rica from 1991 to 2017. *Notes:* the 10 most frequently requested drugs, diagnosis and medical specialties are shown. Approval probability was calculated using all the requests for each of the presented categories. None of the categories show a 0 or 1 approval probability.

Table 3: Descriptive statistics for cancer diagnosis drug requests

No. of requests	1,236			
No. of drugs	161			
No. of drugs requested once	65			
No. of diagnoses	51			
Court decision process	*Mean*	*SD*	*Min*	*Max*
Approval	0.70	0.46	0	1
Appeals	0.06	0.24	0	1
Deliberation time (days)	35.10	33.47	0	329
Individual				
Age	52.87	15.57	2	98
Gender (male=1)	0.35	0.48	0	1
Cancer stage (1 to 4)	3.22	0.82	1	4
Requested drug				
Covered[1]	0.18	0.39	0	1
Never becomes covered	0.42	0.49	0	1
Generic	0.60	0.49	0	1
Same molecule[2]	0.17	0.38	0	1
Symptomatic[3]	0.06	0.24	0	1
Replace current[4]	0.44	0.50	0	1
Economic measures				
Incremental[5] benefits (months)	54.61	8.59	0.00	140.00
Incremental[5] costs (USD)[6]	63,323.83	19,227.35	0.00	166,790.81
Marginal benefits (proportion of remaining expected life)[7]	0.18	0.10	0.00	1.41
Marginal cost (USD)[8]	447,073.16	230,532.21	35,668.03	1,347,743.38
Marginal benefits gained from 10,000 USD[9]	0.03	0.02	0.00	0.28
Months gained from 1,000 USD	0.94	0.39	0.00	5.67

[1] Drug covered by the Public Insurer's benefits package at the time the request was filed.
[2] The requested drug and currently prescribed drug are bio-equivalent.
[3] Requested drug treats symptoms not the cancer itself.
[4] Requested treatment replaces prescribed treatment.
[5] Incremental refers to the difference between requested and prescribed drugs.
[6] Costs are adjusted for inflation to 2017 USD.
[7] Proportion of years out of remaining expected life gained.
[8] Cost of gaining a year of life.
[9] Proportion of years out of remaining expected life gained from 10,000 USD.
Source: primary hand-collected data for drug requests with a cancer diagnosis in Costa Rica from 1991 to 2017.

Table 4: Characteristics of cancer diagnoses observed in Court cases

Diagnoses grouped according to the anatomical system affected	(1) *Number of cases*	(2) *Court cases per 1,000 people*[1]	(3) *Court approval probability*	(4) *Court case mean age*	(5) *Mean diagnosis stage*	(6) *5-year mortality probability*[2]	(7) *Prevalence rate*[3]
Female Reproductive	531	49.93	0.67	54.05	2.96	0.25	192.91
Hematolymphatic	174	6.73	0.80	41.93	2.76	0.18	20.36
Gastrointestinal	163	2.62	0.69	53.96	3.71	0.37	35.15
Male Reproductive	118	8.24	0.68	68.88	3.36	0.25	186.77
Respiratory	59	2.26	0.75	53.73	3.59	0.36	20.80
Urinary	59	3.83	0.76	57.08	3.93	0.29	15.79
Nervous	50	1.88	0.52	44.18	3.70	0.34	11.94
Endocrine	45	2.14	0.73	46.27	3.47	0.23	64.23
Integumentary	24	2.70	0.83	50.67	3.75	0.21	4.34
Musculoskeletal	13	1.18	0.69	29.08	3.77	0.36	1.50

[1] Number of Court cases per 1,000 people with the diagnosis.

[2] Average probability of dying during a 5-year survival period conditional on having the disease, according to sex, 10-year age and calendar year bins.

[3] Average diagnosis prevalence rate per 100,000 people in Costa Rica according to sex, 10-year age and calendar year bins.

Source: primary hand-collected data for all drug requests in Costa Rica from 2009 to 2015, population data from the National Institute for Statistics and Census, and prevalence and mortality data from the Costa Rican Health Ministry's Epidemiological Observatory.

Notes: Cancers included in the endocrine system are neuroendocrine and thyroid; in the gastrointestinal system are appendiceal, colon, gall bladder, gastric, liver, pancreatic, peritoneal, and rectal; in the hematolymphatic system are leukemia, lymphoma, lymphoproliferative disorder, multiple myeloma, and myelodysplastic syndrome; in the integumentary system are melanoma and ocular; in the musculoskeletal system are Ewing sarcoma, Kaposi sarcoma, osteosarcoma, and sarcoma; in the nervous system are astrocytoma, oligoastrocytoma, spinal, tympanic glomus, and other undetermined histopathologies; in the reproductive system -female are breast, endometrial, ovarian, uterine, and vaginal; in the reproductive system -male are prostate and testicular; in the respiratory system are laryngeal, lung, occult primary, oral, and tongue; in the urinary system are kidney and vesical.

1,000 cancer patients) and the hematolymphatic system. The lowest rates are approximately 2 Court cases for every 1,000 patients and correspond to endocrine, gastrointestinal, male reproductive and respiratory systems.

The probability of the Court approving the request for each category is shown in column 3. These range from 0.420 for cancers of the female reproductive system, to 0.921 for cancers of the endocrine system. In column 4 the mean age is presented. None of these values are unexpected, with most being in the middle age range.

In column 5, mean diagnosis stage is shown with the lowest value for hematolymphatic cancers at 2.61. (Note that stage of 3 is considered advanced). Four categories have stages above 3.75 (integumentary, musculoskeletal, nervous, and urinary systems) which indicates cases with high treatment complexity and low cure expectations.

Columns 6 and 7 refer to mortality and prevalence respectively in Costa Rica over the studied period. Mortality was determined as the probability of dying during a five-year survival period conditional on having the disease. Prevalence was determined as a rate over 100,000 persons.

The probability of dying within five-years is between 0.125 and 0.372. These values being mostly similar across categories is supported by good overall country level health outcomes, such as high longevity and readily available health care.

Prevalence rates show a different picture. Reproductive system cancers for both sexes are very prevalent, with rates of above 100 cases per 100,000 people (led by breast cancer for females and prostate cancer for males). Gastrointestinal and endocrine systems have rates of 35 and 64 cases respectively. These values are expected given Costa Rica's morbidity profile which is characterized as a hot-spot for gastric and thyroid cancer (Sierra et al., a,b).

4.7. Stylized facts on litigation

Stylized fact No. 1: No one medical specialty, diagnosis or drug guarantees approval or rejection from the court. From the 26 different medical specialties involved they all have more than 5 cases and none have an approval probability of 0 or 1.

Stylized fact No. 2: Preventive care has the highest approval probability at 0.71; and Nephrology has the lowest at 0.20.

Stylized fact No. 3: For drug requests with 10 or more cases no diagnosis has an approval probability of 0 or 1. (Figure 3 shows data of approval probability by diagnosis and drug).

Stylized fact No. 4: Diazepam and lorazepam are the only 2 out of 663 drugs with a probability of approval of 0 (both are highly addictive benzodiazepines used in the treatment of severe psychiatric diagnoses).

Stylized fact No. 5: Asparaginase, crizotinib, natalizumab, and vemurafenib have an approval probability of 1. All used in the treatment of severe conditions. (The first is a enzymatic supplement used in the treatment of leukemia and lymphoma, the next two are monoclonal antibodies used in the treatment of autoimmune diseases and the last is used to treat skin cancer).

Overall these observations suggest that there are other considerations for the Court beyond specialty, diagnosis and drug.

4.8. Court decision determinants

Figure 4 presents a series of scatter-plots showing the relationship between approval probability (y-axis) and the corresponding measure of benefits and costs (x-axis). Panels A and B use requested drug's incremental benefits and costs. Panels C and D use marginal benefits and costs. Finally, panels E and F provide additional information using measures of marginal benefits gained from 10,000 USD and months gained from 1,000 USD respectively. The solid lines in each plot show generalized linear models approximating the relationship between these variables.

If court decisions were based on one of these specific factors, we'd expect to see a positive correlation with approval probability. Moreover, if the focus was on the individual then approval would be mainly positively correlated to benefits and uncorrelated to costs, which solely impact the PI. On the other hand, if the Court's decisions are more in line with the PI's perspective, then a negative correlation between costs and approval is expected. Furthermore, from the perspective of the PI, if they follow economic evaluation criteria it is a drug's benefit-cost ratio that should be the main determinant factor for a drug being made accessible. We take marginal costs as an approximation of this criterion given that it is the cost of gaining one additional year of life. Further, marginal benefits gained from 10,000 USD serves as an additional way to visualize this.

Visually, we do not observe a strong clear linear relationship with any one of these factors, so far suggesting other considerations beyond these economic measurements for the Court's decision. If we look at the correlation coefficients these are consistently small and are in line with this same idea.

For requested drug incremental benefits and approval probability, there is a slight negative relationship of 0.0019 and for incremental costs there is barely a positive relationship of 0.000002. In a similar fashion, marginal benefits show a negative relationship of 0.3842 with approval probability; and marginal cost's relationship is positive but even slighter 0.0000002. As far as marginal benefits gained from 10,000 USD and months gained from

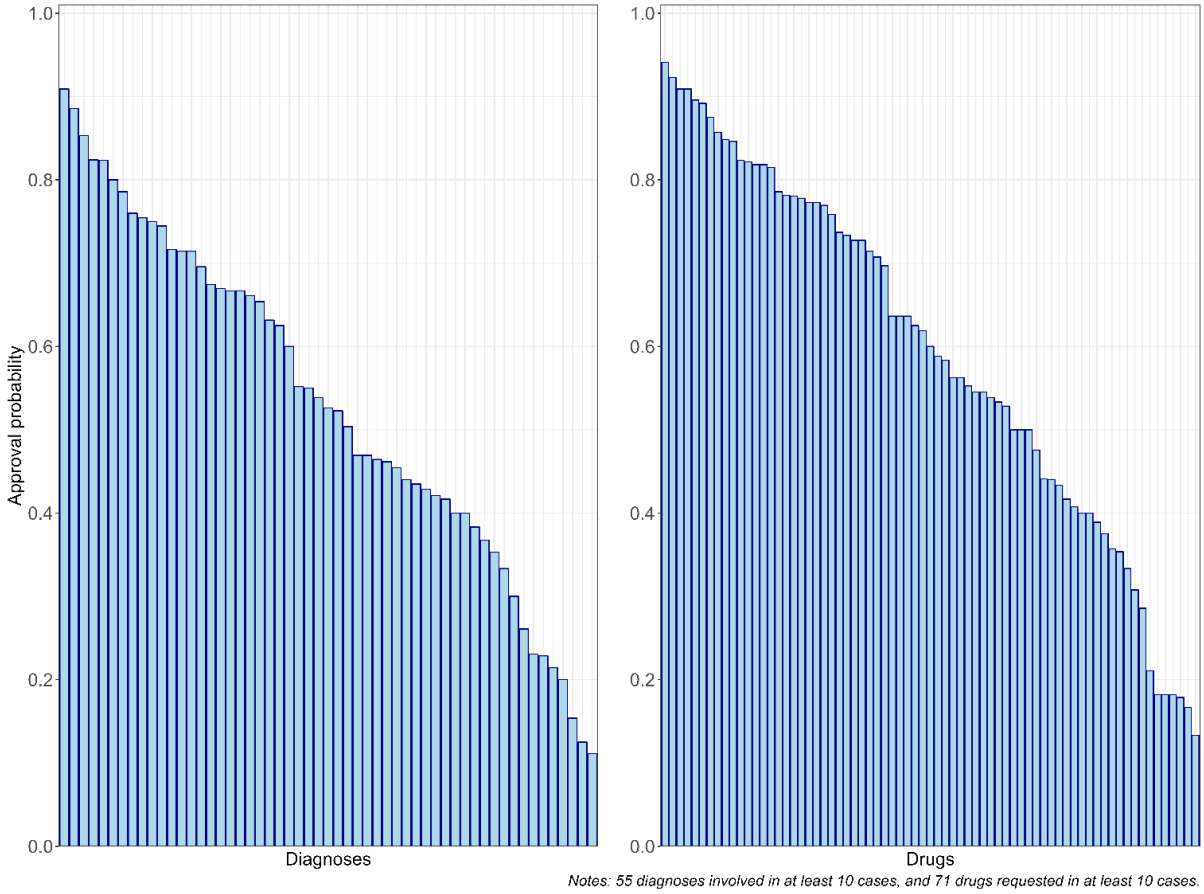

Figure 3: Approval probability by diagnosis and drug for 1,741 cases

Source: primary hand-collected data for all drug requests in Costa Rica from 1991 to 2017. *Notes:* Sample limited to drugs with more than 9 requests (77 different drugs with 1,741 cases among them). Every bar represents all cases for a drug, and no drugs have a probability of 0 or 1.

1,000 USD, the relationships are positive and of a magnitude of 0.1323 and 0.0265.

To further shed some insight into these numbers, first we can look at how costs have a stronger, despite small, correlation to approval probability than benefits. One possible explanation is the role signaling plays as higher costs can be associated to higher potential benefits. Second, costs are potentially capturing part of the effect from benefits if analyzed independently. Finally, it can relate to the nature of a cancer diagnosis, for which complete cures or remission are not the norm (in particular for advanced stage diagnoses, and the data has a mean stage close to 3, considered advanced).

Once we look at approximations to benefit cost ratios, seeing little to no relationship shows that it is not a threshold of this type of factor that likely determines the Court's decision. Essentially this indicates a process distinct from the PI's rationing rules.

4.9. Descriptive evidence on judge reasoning

A lot of evidence was extracted from the court case reports and manually going through these documents gave us further insight into the deliberation process.

Specifically, there is information on the reasoning behind votes against the approval of drug requests. While this will be descriptive anecdotal evidence for now, each report includes the transcript of the justification given during court deliberation, after the vote, where judges can express their opinion and reason for voting against a request.

The way this works is that if a request is approved, but it was not a unanimous decision, the judges that voted 'No' have the option to leave on record why they have voted in such a manner. When this happens, it provides an interesting opportunity to look further into how they evaluate the case and if they factor in some the elements of our interest. Within these statements we can then find insight on the notions judges have on fairness, collective versus individual well-being, scarcity of resources, strain on the system, costs and benefits, and cautionary behavior.

For instance, reading through these cases we see that often judges do highlight that the medical benefits of the drug are not high enough to justify the ex-

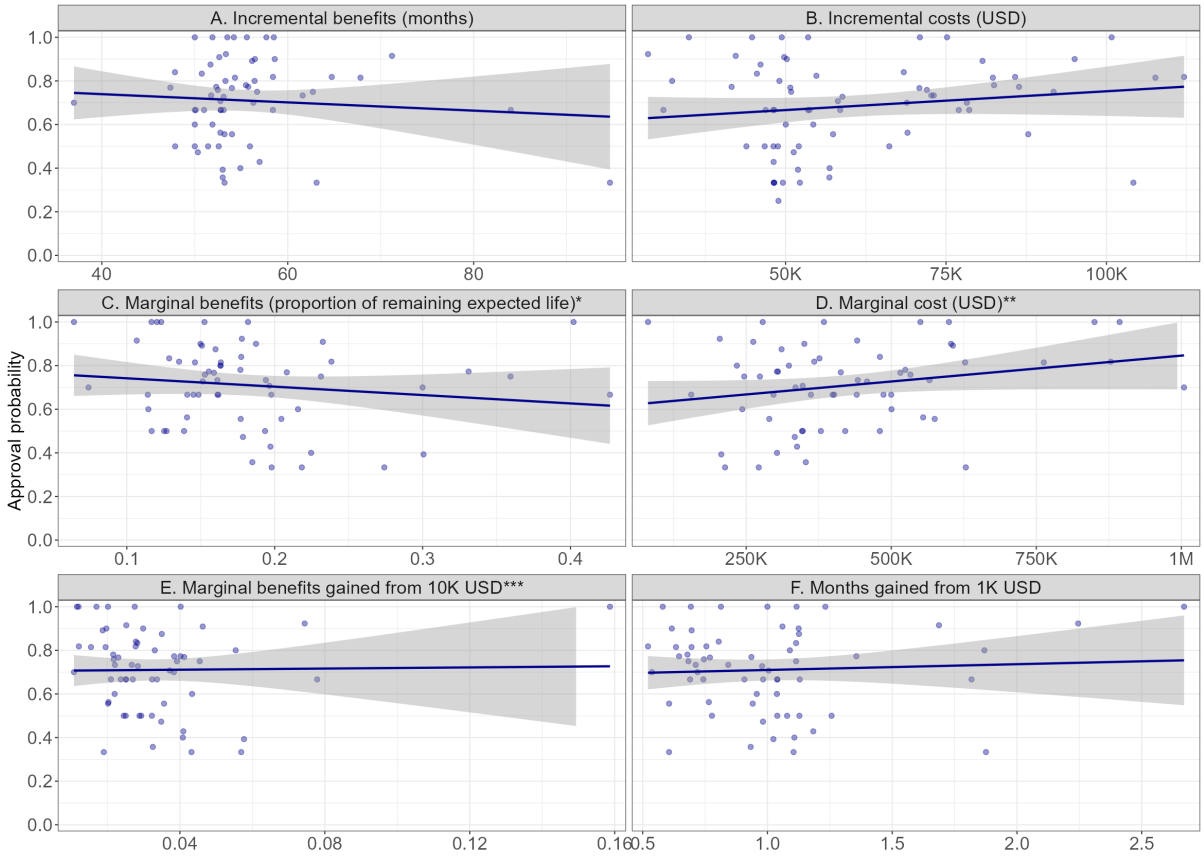

Figure 4: Approval probability and economic measurements

Source: primary hand-collected data for drug requests with a cancer diagnosis in Costa Rica from 1991 to 2017. *Notes:* scatter points each represent average measures over all cases for each drug with more than 6 cases (n = 85). Sample limited to drugs with more than 5 cases. A generalized linear model is shown as a solid line. Benefits measured as progression-free survival months (time from taking the drug before disease progressed); costs adjusted to 2017 dollars; incremental benefits and costs calculated by subtracting the measure for requested minus prescribed drugs.

pense for the insurer. This allows us to see there is some consideration of cost-benefit analyses. Then is it a matter of how it is measured by them, or whether there other factors outweighing this criterion. Alternatively, it may also depend on too few individual judges thinking this way and then the majority vote leading in a different direction.

Another example is that judges often do mention their reservations are rooted in concerns for the scarcity of resources and the proper use of those that are available to the whole population. Concerns mention collective resources in benefit of particular individuals that unfortunately are not in a case they would consider justifies the trade-off. This is insight on their notions of fairness and how to some degree they may align with the public insurer which deals with these issues as they set rationing rules for the whole population. So are judges effectively evaluating individual cases with the evidence presented in front of them or do their considerations go beyond that?

One more recurring element in these texts is also some judges' concerns on the impact of their decisions on future cases. They specifically draw attention to if they are setting legal precedent for more patients to make these type of requests and their inability to cover all of them in the future. This would provide some insight on the concerns of the effects on litigation cases and future trends in drug requests. This is a reflection of cautionary behavior. Particularly with the caution principle, there is in theory a contrast between decision makers focused on maximizing social welfare, and individual perspectives, as that of judges in this case. Reading these statements further goes to the point of thinking on the collective rather than solely on the individual patient in some cases.

Overall, the different elements reflect caution given the context of the legal system as well as economic analysis elements such as opportunity costs and effectiveness analysis. An interesting extension would be to use text analysis to identify the occurrence of

key words or phrases (as those exemplified above) that could provide an approximation of what factors into judges' decisions. Other than those noted while reviewing manually these reports, this analysis could also bring to light other elements that have not been identified so far but that could be useful to understand court deliberation.

5. Methods

Following the descriptive analysis to understand litigation for access to drugs and how the phenomenon manifests, we continue with Probit models to explore the data predicting court approval probability.

5.1. Model for Court approval probability

To study the factors that determine Court approval, we examine a model where the dependent variable is the Court's decision to approve or not each request for a drug. The dependent variable is assigned a value of 1 if the request was approved for case i and 0 if rejected. The specification of this binary variable for the probit model is as follows

$$decision_i = \beta_0 + \sum_{j=1}^{k} \beta_j X_{ij} + \epsilon_i, \qquad i = 1, ..., 1236 \tag{1}$$

where *decision* is a binary dependent variable, X's are independent variables hypothesized to affect approval probability for a drug request, ϵ_i is a normally distributed error term, and the β's are coefficients obtained through maximum likelihood estimation. More specifically, the form of the equation estimated is:

$$decision_i = \beta_0 + \beta_1 pred_i + \beta_2 X_i + \tau_t + \gamma_i + \delta_g + \epsilon_{id} \tag{2}$$

where the subscript i represents the case number, τ are year fixed effects, γ are judge fixed effects, δ are diagnosis fixed effects, and ϵ_{id} are robust standard errors clustered at drug level.

The main explanatory variables are represented by $pred_i$ and there are two different cases. In one specification, incremental benefits and costs are used, and in the other, benefits to costs ratio is used. All three variables were standardized so the resulting coefficients could be interpreted as a change of 1 standard deviation.

For every specification control variables X_i include: individual (age, gender, stage), drug (generic, same molecule, symptomatic, substitute), coverage status and court process (deliberation time, defense, appeal) variables.

Marginal effects were estimated for each specification to predict effects on Court approval probability. Additional specifications were run using as main explanatory variables requested drug benefits and costs, and sub-setting requests to only cases with early stage diagnoses.

5.2. Model for prevalence and mortality

To begin, there is a descriptive analysis to observe prevalence and the probability of dying in relation to the diagnoses involved in litigation cases requesting drugs for cancer treatment. Prevalence rates and the probability of dying for each diagnosis were classified using terciles to create high, mid, and low categories.

Then, to determine the possible role of prevalence and mortality in Court decisions, an econometric model predicts approval (indicated by the binary variable *decision*, where approval is 1, and rejection is 0). The main predictors (*pred*) of interest are prevalence, included as a rate, and mortality, included as the probability of dying.

Both variables are adjusted by sex, age, and are cause specific as described in the data section. As an example, for case i which involves a 54 year old woman with rectal cancer in year t, the associated prevalence rate and probability of dying will be adjusted to a woman in the 50 to 60 age group and be specific to rectal cancer for year t.

Each predictor is included in the model separately, thus the probit model is as follows:

$$decision_i = \beta_0 + \beta_1 pred_i + \beta_2 ben_i + \beta_3 costs_i + \beta_4 X_i + \tau_t + \epsilon_i \tag{3}$$

where the X's are control variables, the subscript i represents a case, τ_t are year fixed effects, and ϵ_i is an error term.

Incremental benefits (*ben*) and costs (*costs*) are standardized so that the resulting coefficients can be interpreted as a change of a standard deviation. For benefits this is 13 months of survival without cancer progression, and for costs this means 17,600 USD.

For every specification control variables in X_i include individual, drug, diagnosis, and court process variables. Marginal effects were estimated for each specification in order to predict effects on the likelihood that the Court approves a drug request.

5.3. Model for drugs gaining coverage and litigation

In order to examine how Court requests' trends change relative to a drug gaining coverage an event study model is used. The hypothesis is that drug requests increase until the public insurer grants coverage, and afterwards requests decrease if litigation is responding to drugs gaining coverage.

The event is defined as the month when a drug gains coverage. This uses all 63 drugs that were uncovered at the time of the claim, if the observation is that they

then gain coverage. The control drugs are the requests for those that never gain coverage. With this set up it is possible to analyze the coefficients on indicator variables for time relative to the event. The event study specification is as follows:

$$y_{dt} = coverage_{dt} + \left[\sum_{r=-143}^{-2} \beta_r I(t - t_d^* = r) + \sum_{r=0}^{145} \beta_r I(t - t_d^* = r) \right] + \epsilon_{dt} \quad (4)$$

Here d is drug; t is month; y_{dt} is the outcome of drug-month requests (meaning if the case is approved); and I is an indicator function measuring time relative to the implementation period t_d^*. The variable $coverage_d$ is 1 if drug d is covered in time t and 0 if it is not covered. Then, ϵ_{dt} are drug-month standard errors. Lastly, the omitted category (β_{-1}) is the month prior to a drug gaining coverage.

The main interest is on the pattern of the coefficients β_y which estimate the outcome at a given t relative to the omitted category β_{-1}. The advantage of this model is that it allows to visually assess the pattern of requests relative to the date of drugs gaining coverage (Dobkin et al., 2018; Freyaldenhoven et al., 2019).

6. Results

The main results are presented in Tables 5 and 6. These consist of marginal effects on approval probability through 8 models that test different determinant factors as outlined in the previous sections and specifically from the probit model in equation 3. Table 5 contains the marginal effects on Court approval for all cases while Table 6 has marginal effects on Court approval probability only for the sub-sample of late stage cancer cases (stages 3 and 4). Every estimation of the models includes year and judge fixed effects and a set of controls as described in section 4. Columns 4 and 5 present specifications with hospital and diagnosis fixed effects as well.

Specification in column 1 includes no controls. Specification in column 2 includes controls for individual characteristics of age, gender, and cancer stage. Specification 3 additionally includes controls for drug characteristics (generic, same molecule, symptomatic treatment, substitute treatment and covered/never covered).

Every specification was evaluated using log-likelihood tests, pseudo R^2 and Akaike information criterion, with all showing similar results but the first three specifications (columns 1 to 3) having slightly better explanatory power and column 3 as the preferred specification. Even though results are consistent throughout all specifications, Court process variables could suffer from endogeneity concerns due to unobserved Court process characteristics.

Regarding individual variables, age and gender have small and non-significant effects on approval probability. Looking at stage, which is possibly capturing the any relevant effects from age and gender, this is positive and significant but only when not including drug controls.

Looking at these controls we see that when the treatment requested is for the same molecule or for a symptomatic treatment this reduces the probability of approval. However, effects from substitute treatment and coverage do not appear significant. By definition, requesting the same molecule and symptomatic treatment provide no incremental benefits for a cancer diagnosis and, as such, their effects being negative, significant and large fits with the results that benefits matter for Court decisions.

Requesting a covered drug had a negative not significant effect on approval probability; and requesting a never covered drug had a positive barely significant effect. As mentioned before, a drug already covered by the PI is requested via litigation when the use is not covered or when a specific brand is being requested. Given the hypothesized direct link between coverage and litigation, it is surprising that the effect is not significant. The negative direction of the effect suggests that alternative uses and specific brands do not help make the case for access to a drug from the Court's perspective.

Additional specifications tested the influence of employment categories (White Collar, Unemployed, Retired, Blue Collar, Student), disability status, economic vulnerability (high or low), medical provider (Referral Hospital, Regional Hospital, Specialized Clinic, General Practice), Claimant Affiliation (Self, Third Party, Family, Lawyer, Government) and region (7 provinces as well as rural versus urban classification). From the analysis, none of these factors for cultural and socioeconomic background were salient determinants of approval by the Court.

As for a drug never gaining coverage (up until February 2019), it is interesting that the effect is positive. This could suggest that a drug being covered gives a specific context for the drug and the Court does consider this, but a never covered drug has no background decision about how to use it. However, further evidence is needed to be able to fully understand this relationship.

6.1. Predicting Court approval probability using marginal costs and benefits

Models 4 and 5 test for the effects from marginal benefits and marginal costs. Recall that marginal costs are defined as the cost of gaining a year of life, which is essentially a measure that approximates cost-benefit ratios that are a PI's main criterion.

For marginal benefits, the results do not show any significant effects across any of the specifications in-

Table 5: Marginal effects on Court approval probability

	(1)	(2)	(3)	(4)	(5)
Model 1					
Diagnosis prevalence[1]	−0.0004***	−0.0003*	−0.0002	−0.0004	−0.0004
	(0.0001)	(0.0002)	(0.0002)	(0.0004)	(0.0004)
Model 2					
Probability of dying[2]	−0.2652	−0.2694	−0.2390	−0.0244	0.0070
	(0.1804)	(0.1819)	(0.1774)	(0.3147)	(0.3147)
Model 3					
Diagnosis prevalence[1]	−0.0005**	−0.0004**	−0.0003*	−0.0006	−0.0005
	(0.0001)	(0.0002)	(0.0002)	(0.0004)	(0.0004)
Probability of dying[2]	−0.4412***	−0.3963**	−0.3442*	−0.1574	−0.1117
	(0.1907)	(0.1920)	(0.1866)	(0.3298)	(0.3296)
Model 4					
Marginal benefits[3]	0.0263	0.3456	0.1992	−0.0215	0.0446
	(0.1292)	(0.3564)	(0.3299)	(0.3137)	(0.3173)
Model 5					
Marginal costs[4]	0.0504**	0.0884**	0.0791*	0.0802*	0.0758*
	(0.0245)	(0.0429)	(0.0420)	(0.0428)	(0.0426)
Year fixed effects	X	X	X	X	X
Judge fixed effects	X	X	X	X	X
Hospital fixed effects				X	X
Diagnosis fixed effects				X	X

[1] Average diagnosis prevalence rate per 100,000 people in Costa Rica according to sex, 10-year age and calendar year bins.
[2] Average probability of dying during a 5-year survival period conditional on having the disease, according to sex, 10-year age and calendar year bins.
[3] Proportion of years out of remaining expected life gained.
[4] Cost of gaining a year of life.
Source: primary hand-collected data for drug requests with a cancer diagnosis in Costa Rica from 1991 to 2017. *Notes:* all columns report effects based on probit regression estimates of equation (1). Robust standard errors clustered at the drug level are in parentheses. Significance levels are shown as *** for a $p < 0.01$, ** for a $p < 0.05$, and * for a $p < 0.1$.

cluded. As for marginal costs, there are small yet significant effects for 3 out of the 5 specifications. This firstly indicates that the Court is not taking a decision that simply changes the threshold of cost-benefit ratio to approve a treatment when compared to the PI.

Small or insignificant effects from benefits would be unexpected if the narrative is that expected benefits from drug treatments are supposed to explain the Court's decisions. Hence the explanation that individual benefits drive Court decisions is insufficient. With the effects from costs on approval, it indicates that, at least as a panel, judges are not primarily driven by a concern for the costs of these treatments to make their decisions. Moreover, such effects in any case appear in favor of approval as an increase of 1 standard deviation increases approval probability by 7.91 percentage points in the preferred specification at a p=0.10 level of significance.

6.2. Predicting court approval with prevalence and mortality

The results of using terciles to classify diagnoses into groups according to prevalence and mortality are shown in Table 7. Each panel shows a different mortality level, and the mean value for this can be seen in column 4 (it decreases between panels). Within each panel, every row represents a decreasing level of prevalence, and the mean values for this can be seen in column 5 (decreasing within the panel).

The diagnoses groups in each panel and row are as would be expected from standard medical practice (Bray et al.) and Costa Rican cancer profiles (Global Health Observatory, 2015). In column 2 we see the number of Court cases per 1,000 people with the diagnosis.

In column 3, the probability of drug requests being approved by the Court for each group is reported. Panels A and B show similar high probabilities, while the last panel for low mortality has lower probabilities. Within panels, there is no consistent pattern for

Table 6: Marginal effects on Court approval probability for late stage[1] cancer cases

	(1)	(2)	(3)	(4)	(5)
Model 1					
Diagnosis prevalence[2]	−0.0002	−0.0002	−0.0001	0.0003	−0.0003
	(0.0002)	(0.0002)	(0.0002)	(0.0004)	(0.0004)
Model 2					
Probability of dying[3]	−0.3421*	−0.3441*	−0.2596	−0.1291	−0.0932
	(0.1838)	(0.1858)	(0.1818)	(0.3191)	(0.3196)
Model 3					
Diagnosis prevalence[2]	−0.0003*	−0.0003*	−0.0002	−0.0005	−0.0005
	(0.0002)	(0.0002)	(0.0002)	(0.0004)	(0.0004)
Probability of dying[3]	−0.4606**	−0.4598*	−0.3505*	−0.2564	−0.2118
	(0.1973)	(0.1997)	(0.1950)	(0.3352)	(0.3358)
Model 4					
Marginal benefits[4]	0.0918	0.5157	0.2971	0.1452	0.2452
	(0.1418)	(0.4270)	(0.3850)	(0.3666)	(0.3823)
Model 5					
Marginal costs[5]	0.0414	0.0945**	0.0780*	0.0773*	0.0673
	(0.0271)	(0.0459)	(0.0449)	(0.0465)	(0.0466)
Year fixed effects	X	X	X	X	X
Judge fixed effects	X	X	X	X	X
Hospital fixed effects				X	X
Diagnosis fixed effects				X	X

[1] Cancer stages range from 1 to 4 (most severe). This table shows results for cases of stages 3 and 4 diagnoses.
[2] Average diagnosis prevalence rate per 100,000 people in Costa Rica according to sex, 10-year age and calendar year bins.
[3] Average probability of dying during a 5-year survival period conditional on having the disease, according to sex, 10-year age and calendar year bins.
[4] Proportion of years out of remaining expected life gained.
[5] Cost of gaining a year of life.
Source: primary hand-collected data for drug requests with a cancer diagnosis in Costa Rica from 1991 to 2017. *Notes:* all columns report effects based on probit regression estimates of equation (1). Robust standard errors clustered at the drug level are in parentheses. Significance levels are shown as *** for a $p < 0.01$, ** for a $p < 0.05$, and * for a $p < 0.1$.

Table 7: Diagnoses in Court cases according to prevalence and mortality levels (defined using terciles)

Prevalence level[1]	*Diagnosis*		(1) *Number of Court cases*	(2) *Court cases per 1,000 people*[2]	(3) *Court approval probability*	(4) *5-year mortality probability*[3]	(5) *Prevalence rate*[4]
	Panel A. High mortality level[1]						
High	Lung Cancer	Occult Primary	49	1.69	0.87	0.38	24.67
Mid	Liver Cancer	Pancreatic Cancer	51	2.61	0.67	0.48	15.56
Low	Sarcomas[5]	Peritoneal Cancer	11	1.26	0.47	0.44	1.38
	Panel B. Mid mortality level[1]						
High	Breast Cancer Endometrial Cancer Thyroid Cancer	Colon Cancer Gastric Cancer Uterine Cancer	614	10.97	0.52	0.26	98.52
Mid	CNS Cancer -Supratentorial[6] Kidney and Vesical Cancer Leukemia and Multiple Myeloma Ovarian and Vaginal Cancer Testicular Cancer	Gall Bladder Cancer Orolaryngeal Cancer[7] Melanoma Rectal Cancer	332	2.02	0.70	0.28	11.77
Low	Appendiceal Cancer Neuroendocrine Tumor Osteosarcoma	Kaposi Sarcoma Ocular Tumor Spinal Cancer	21	0.98	0.54	0.25	1.22
	Panel C. Low mortality level[1]						
High	Lymphoma	Prostate Cancer	150	6.28	0.76	0.07	108.51
Mid	Myelodysplastic Syndrome		6	1.08	0.50	0.01	9.11
Low	Lymphoproliferative Disorder	Tympanic Glomus	2	0.81	0.00	0.11	0.62

[1] Levels determined using terciles to classify the diagnoses' prevalence and probability of dying over all diagnoses observed in Court cases.
[2] Number of Court cases per 1,000 people with the diagnosis.
[3] Average probability of dying during a 5-year survival period conditional on having the disease, according to sex, 10-year age and calendar year bins.
[4] Average diagnosis prevalence rate per 100,000 people in Costa Rica according to sex, 10-year age and calendar year bins.
[5] Includes sarcomas except Kaposi and osteosarcomas (*i.e.* soft-tissue and Ewing sarcomas).
[6] Central nervous system cancers supratentorial includes astrocytomas, glioblastomas, oligoastrocytomas, and other cancers of the nervous system with undetermined histopathologies.
[7] Includes oral, tongue and laryngeal cancers.
Source: primary hand-collected data for all drug requests in Costa Rica from 2009 to 2015, population data from the National Institute for Statistics and Census, and prevalence and mortality data from the Costa Rican Health Ministry's Epidemiological Observatory.

the rate of cases (column 2) or approval probabilities (column 3), so there does not appear to be different behaviors between rare and common cancers.

Figure 5 shows diagnoses scattered across mortality and prevalence with the size of the shape showing diagnosis specific court approval probability. Overall this shows no salient pattern. Using predicted Court approval probability Figure 6 shows the lower right area with slightly higher concentration of higher predicted approval but it is not exclusive to this quadrant. More generally, we observe a more clear distinction with respect to mortality, with lower mortality having great approval probability. As for prevalence, no clear pattern appears. This relationship will be further examined with the analysis of Court decisions in models 1, 2 and 3.

6.3. Likelihood of Court approval using prevalence and mortality as predictors

Models 1, 2 and 3 in Table 5 provide the different specifications testing how prevalence or mortality may play a role. Model 1 and 2 include only prevalence and only mortality respectively, while model 3 includes both predictors.

Increasing cancer diagnosis prevalence (more common diseases) decreases the likelihood of approval for a case but this is a small and negligible effect while significant only for the first two specifications. The sign of the change matches the prediction that the more common a diagnosis, the lower the approval probability if caution plays a significant role. Here marginal effects are too small for it to be reasonable to conclude that prevalence is a main factor in judges' decision process. For model 3, it appears significant for the first three specifications, but remains negligible.

Models for mortality then show that the more lethal a disease, the lower the likelihood that a request is approved. In model 2, the probability of dying does not appear significant. However, in model 3 the probability of dying is significant across the first three specifications. We see that more lethal diseases lower the probability of approval by 44.12, 39.63 and 34.42 percentage points respectively. Once we move on to specifications 4-5 (including hospital and diagnosis fixed effects) these effects are still negative but smaller and non significant.

First off, this indicates that lethality does not work by inducing sympathy in judges resulting in high approval probabilities (which is a common general public concern). It does support the previous finding that the likelihood of approval increases when a request has a higher survival rate.

This finding was observed in terms of higher benefit drugs and requests for additional curative treatments being more likely to be approved. Additionally, requests that did not have a clear path to cure the cancer were less likely to be approved. From the result that increased mortality decreases approval probability, it appears that sympathy does not play a role or that it is overpowered by the value placed by judges on the possibility of survival. Higher mortality means less chances of survival, and results in lower likelihood that a request is approved.

Further insight into the benefits and costs relationship with prevalence and mortality can be found in Figure 7, where diagnoses are plotted with their average requested treatment incremental cost-benefit ratios (ICBRs) as a size scale. Note that higher mortality (and prevalence for that matter) results in higher ICBRs (larger sized circles).

6.4. Marginal effects for late stage cancer cases

Cancer diagnosis stage had some small yet positive effects on approval probability in our estimations. The magnitude and sign would suggest more advanced diseases increase the likelihood that the Court approves a request. Advanced stage diagnosis could suggest a higher degree of cases where the requests are a *"last resort"*. Here it may be that benefits will be smaller but less alternatives are available as a way of treatment. The same specifications are run on a subset of cases with stages of 3 or 4.

When looking at marginal costs and benefits, results are relatively similar. However, when looking at prevalence and mortality, these change somewhat. For prevalence, effects no longer appear significant for model 1 (even if negligible to start with) and are even smaller and less significant than in the previous results for model 3.

For mortality, in model 2 the effects for specifications 1 and 2 are now significant and larger (increasing likelihood of approval by close to 34 percentage points). Once we move on to specification 3 (including drug controls) and 4-5 (including hospital and diagnosis fixed effects) these effects are still negative but smaller and non significant. Looking at model 3, the general result holds up with a significant and negative effect from mortality on approval probability in specifications 1-3 (lowering likelihood of approval by 46.06, 45.98 and 35.05 percentage points respectively in each specification). For specifications 4 and 5 it remains negative and large (25.64 and 21.18 percentage points respectively) but non significant.

6.5. Event study model for drugs gaining coverage

When understanding how litigation serves as a safety valve, it is necessary to consider the impact on future decision making given past outcomes from litigation and hence the implications for future rationing by the public insurer given the scarcity of resources. The event study provides further insight into litigation as a rationing mechanism with the case of trends observed in Costa Rica.

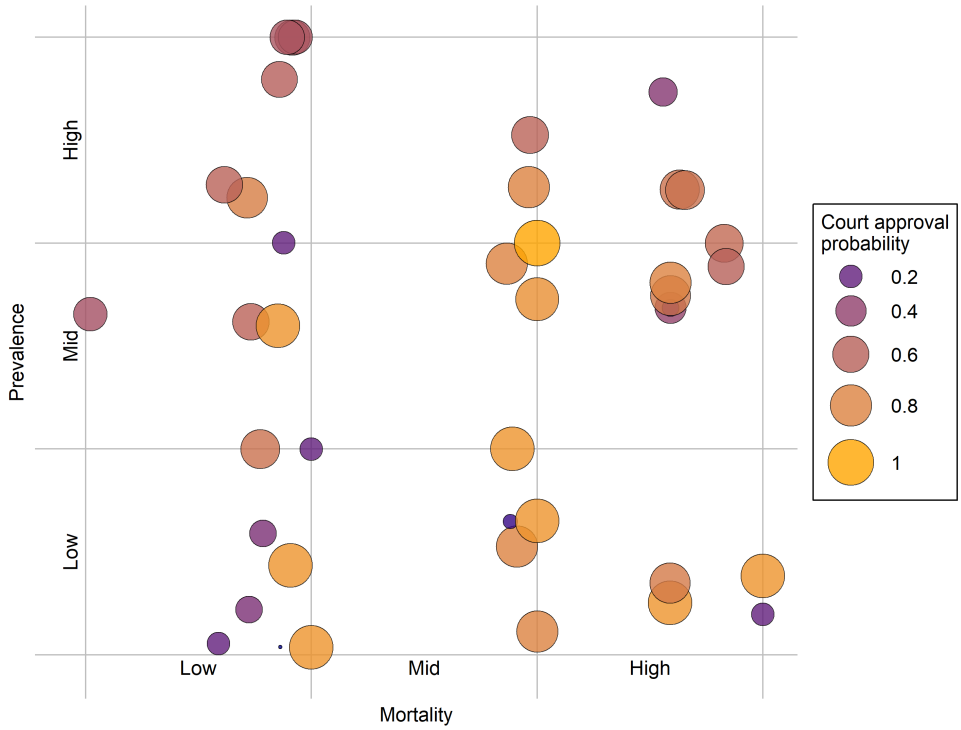

Figure 5: Diagnoses classified according to prevalence and mortality terciles with the diagnosis' Court approval probability

Notes: Prevalence and mortality classified using terciles (divided by solid grid lines). Cases (n = 686) collapsed by diagnosis (n = 41). Each diagnosis is plotted onto the grid with its size corresponding to the diagnosis' likelihood of approval by the Court.

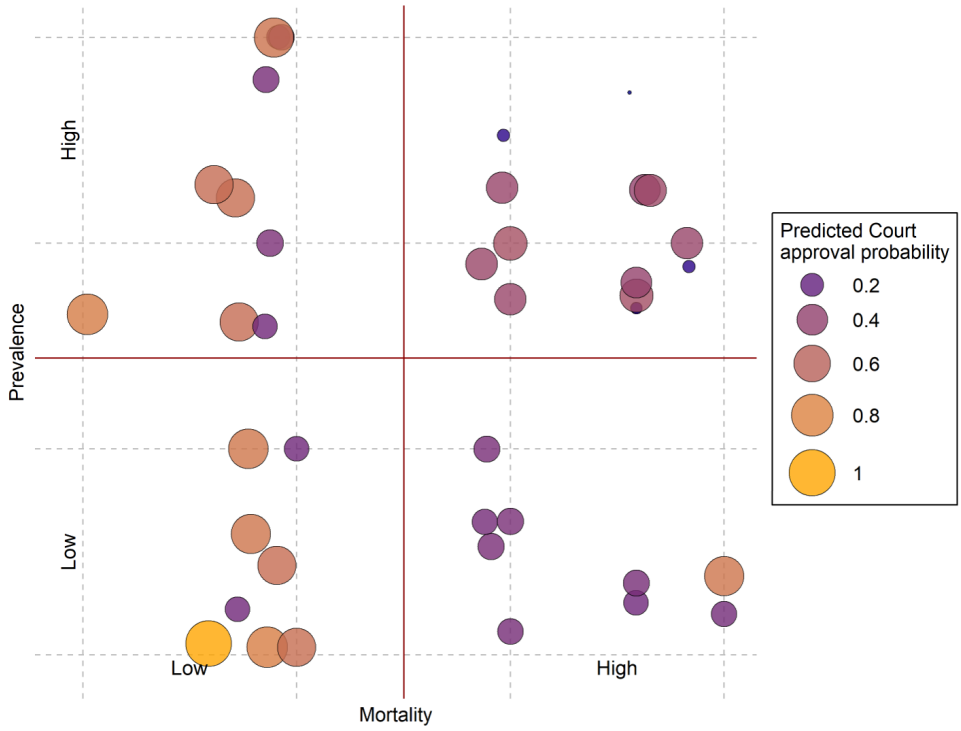

Figure 6: Diagnoses classified according to prevalence and mortality terciles with the diagnosis' predicted Court approval probability

Notes: Prevalence and mortality classified using terciles (divided by solid grid lines). Cases (n = 686) collapsed by diagnosis (n = 41). Each diagnosis is plotted onto the grid with its size corresponding to the diagnosis' likelihood of approval by the Court.

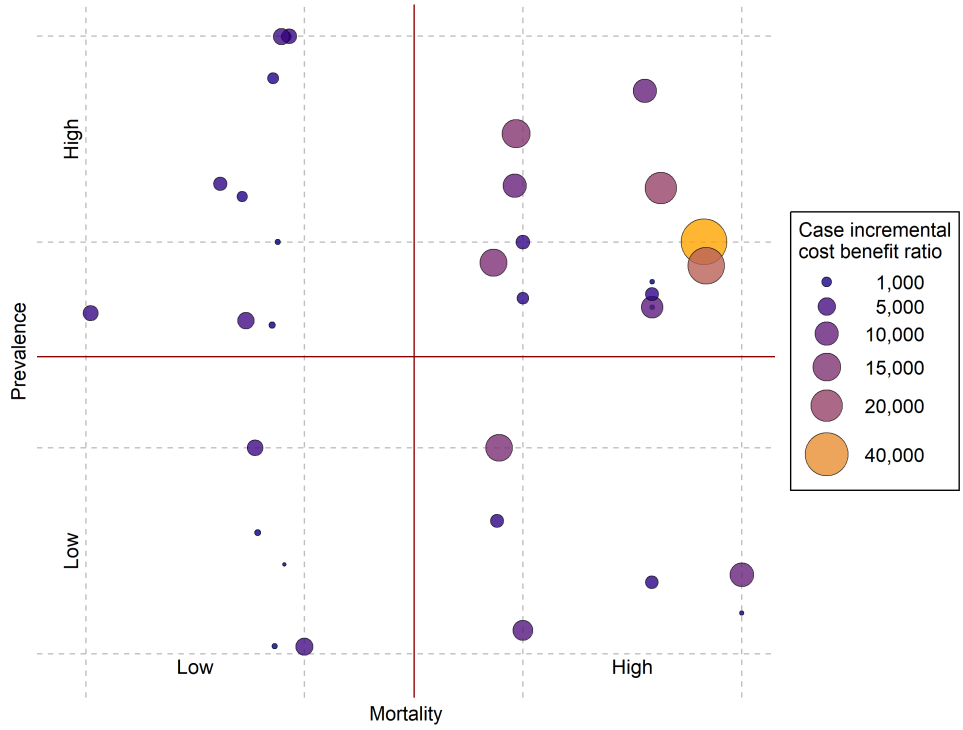

Figure 7: Diagnoses classified according to prevalence and mortality terciles with the diagnosis' ICBR

Notes: Prevalence and mortality classified using terciles (divided by solid grid lines). Cases (n = 686) collapsed by diagnosis (n = 41). Each diagnosis is plotted onto the grid with its size corresponding to the diagnosis' likelihood of approval by the Court.

The first part of the results include a descriptive visual analysis of approval probability over time for drugs. In Figure 8 approval probabilities for a sample set of 6 drugs are plotted as a solid line with the y-axis as approval probability and the x-axis as the years since they were first requested. Each panel in this figure presents a different drug. If legal precedent were a salient consideration for the Court, we would expect the line to flatten. This is not observed in the data plotted. In Figure 9 the grouping of drugs is by those for cancer or non-cancer treatments. Once more the plotted lines for each group of drugs does not flatten.

Second, to examine legal precedent further, each drug was set up as a time series and aggregated using the first year a drug is requested as 0. An autocorrelation function estimates coefficients for the correlation between the observed time series and itself with a lag (as with the event study described in equation 4).

These results for a lag of 1 year can be seen in Figure 10. The estimates of the effects of legal precedent are on the y-axis and the years after the first request are on the x-axis. At lag 0 the correlation is 1, as is as expected by definition since the data is correlated with itself perfectly. Then for all subsequent years the results lie within the 95% confidence interval bounds. These bounds are shown as the dotted horizontal lines in the figure. These results held when introducing lags of 5 and 10 years.

This analysis indicates that legal precedent doesn't appear to play a salient role in Court decisions. In addition to the previous fact, this may suggest that the Court likely takes into consideration individual case characteristics when making decisions on drug requests.

6.5.1. Court requests and PI coverage

There are key potential implications of a possible link between (1) litigation volume and case resolutions, and (2) the public insurer's decisions on coverage. However, this relationship between the amount of litigation for a drug and the drug gaining coverage is unknown. If it does exist, it is plausible to expect a type of *dose response behavior*. Here drug requests would increase up to the point in time when they gain coverage. Before coverage, this is observed as an upward trend in the amount of litigation. The underlying mechanism would be that requests trigger a review of evidence by the public insurer. As the insurer reviews the evidence for the drug requested in court, this may create an incentive for the insurer to change its coverage status.

After a drug gains coverage it is expected that re-

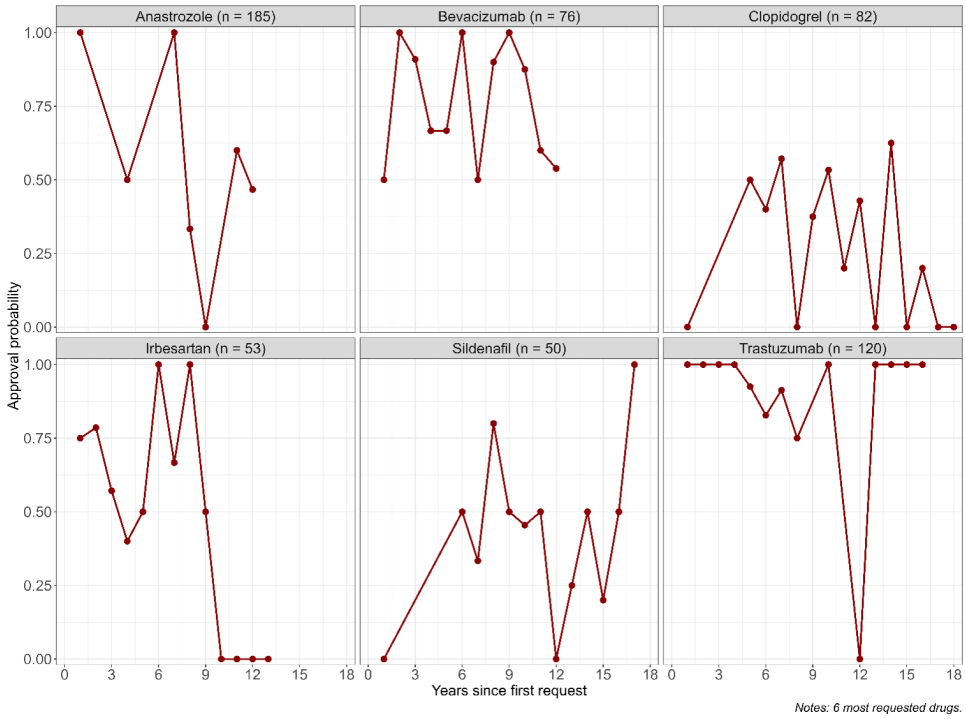

Figure 8: Approval probability of selected requested drugs over time

Source: primary hand-collected data for all drug requests in Costa Rica from 1991 to 2017. *Notes:* All cases for a drug are defined as a time series and plotted independently. The 6 selected drugs are among those with the highest number of cases and are meant as examples. If Court decisions on one year affect subsequent decisions the trend over time would be horizontal.

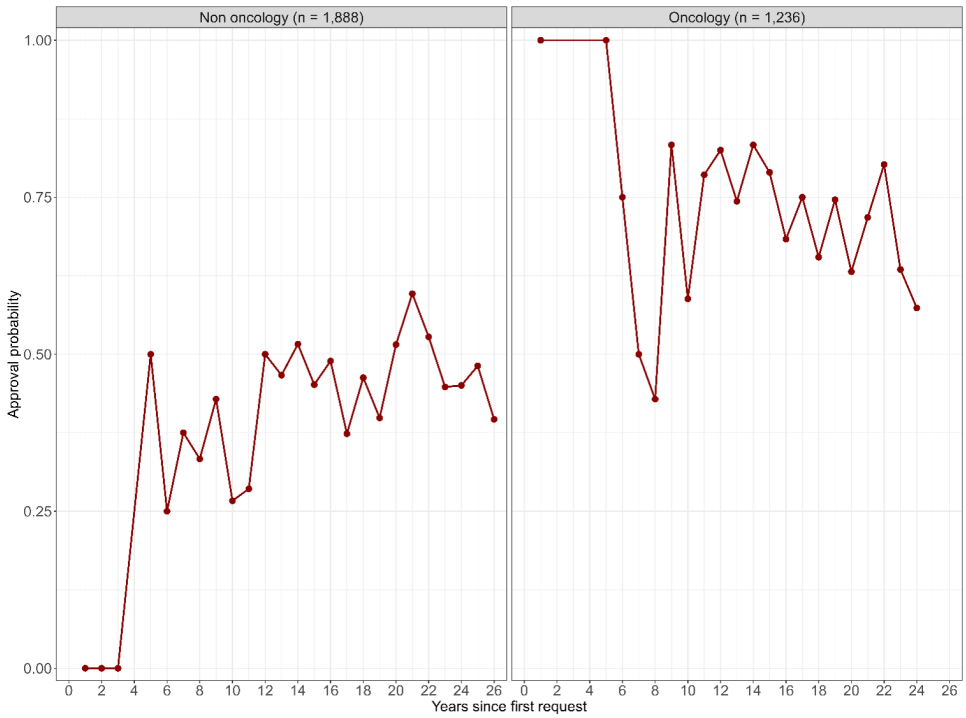

Figure 9: Approval probability of requested drugs classified into cancer or not cancer drugs over time

Source: primary hand-collected data for all requests in Costa Rica from 1991 to 2017. *Notes:* All cases for a drug are defined as a time series and aggregated according to if they are or not cancer treatment drugs. Each category was plotted independently. If Court decisions on one year affect subsequent decisions the trend over time would be horizontal.

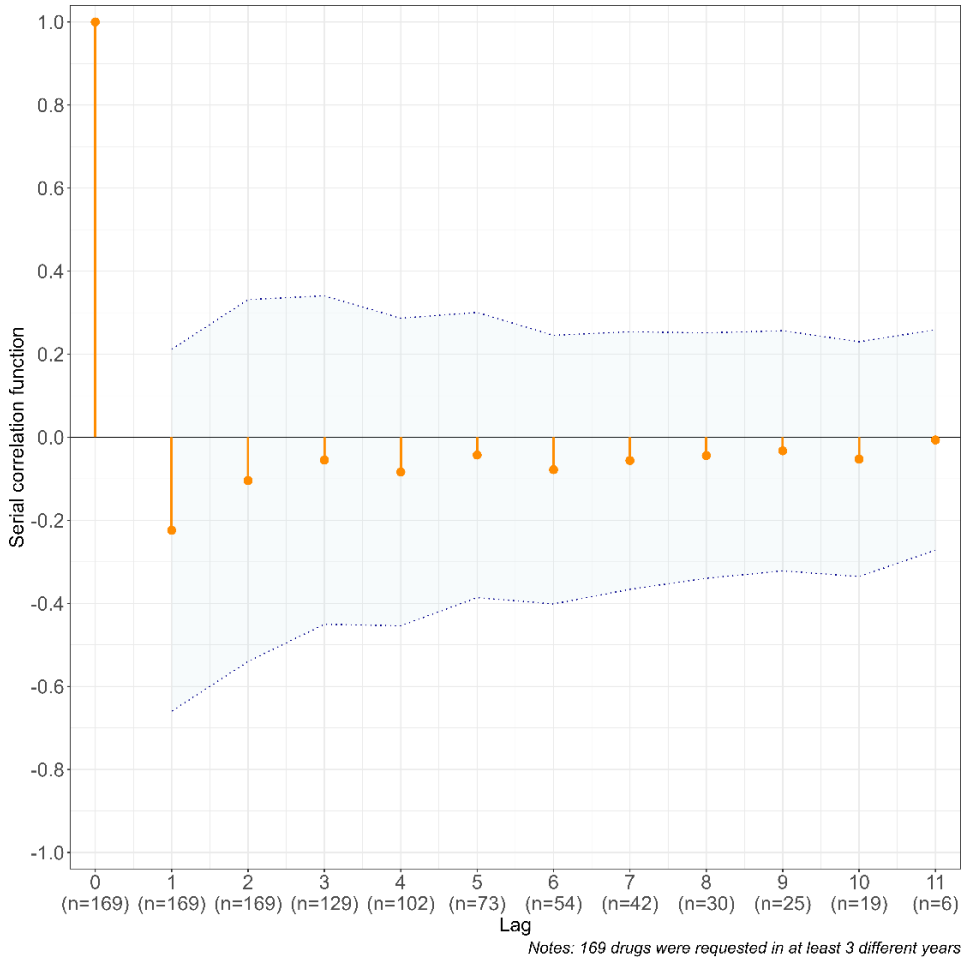

Figure 10: Estimates of legal precedent effects on drug approval probability, time series with a lag of 1 year (drugs = 269)

Source: primary hand-collected data for all drug requests in Costa Rica from 1991 to 2017. *Notes:* 95% confidence interval shown by horizontal dashed lines. Year 0 shows a correlation of 1 by design (data correlates with itself). All drugs with more than 5 requests (n=269) were organized as time series and aggregated based on the year of the first request being defined as 0.

quests decrease. Without a higher degree of rationing for this drug now more readily available, there is a smaller need for litigation as a safety valve in these cases. An alternative scenario that may result is that the drug, now on the list, is being requested for alternate uses other than the one for which coverage was granted. In this case it may instead lead to an increase in requests post change in coverage. Additionally, increased attention to the drug as it gains coverage could have an incremental effect on requests for alternate uses.

We present the results of the event study examining Court requests relative to when drugs gain coverage. A visual inspection of the coefficients does not show a clear pattern on either side of the event. It is important to note that given the structure of the system and mechanism described for Costa Rica, the most direct way for the public insurer to impact drug requests is through changes in drug coverage status. Since the evidence does not suggest a relationship between these variables, it may not be of central interest for the insurer to do so, or there may be other limitations of resources and caution that predominate. This result is also a reflection of the differences found so far between the decision criteria used by the insurer (economic analyses by ordinance) in contrast with the Court's.

6.5.2. Approximation of court cost-effectiveness

A standard for economic evaluations of health care is using incremental cost-effectiveness ratios (ICERs) to determine whether an intervention should be covered by a public insurer. The role of ICERs was discussed previously, highlighting their role as estimates of the economic value of medical interventions and their set thresholds as rules for rationing policy in health care systems. Using the data from the Court's decisions, approved cases have an average

ICER of 3,603 dollars per month. In comparison, rejected cases have an average ICER of 3,414 dollars per month. Hence, approved cases have higher ICERs than rejected cases. This first approximation is interesting as it can add to the evidence that the main criteria for rulings are not the traditional variables in economic analyses. The discerning information for judges to make rulings is resulting in the approval of cases that have higher ICERs. Approving coverage for interventions with higher ratios is in contradiction with the public insurer's main criterion for rationing and has consequences on the resources available for use in the system.

How do these numbers fit within evaluations of healthcare systems around the world? A first point of reference is the World Health Organization (WHO). The WHO recommends that health care systems cover interventions with per year ICERs less than 3 times a country's gross domestic product (Marseille et al., 2015). For Costa Rica this corresponds to interventions with ICERs under 2,433 dollars. The Court's approved cases' ICERs then do not pass the WHO's rule as they would not be recommended for coverage based on the criteria described here.

A second point of reference is the United Kingdom's healthcare system. Here, the National Institute for Health and Care Excellence uses a standard threshold of 25,666 to 38,499 dollars yearly ICER (Paulden, 2017), which corresponds to 2,139 to 3,208 monthly. Once more the cases approved by the court exceed these thresholds and would not be recommended to be covered by the health care system. Additionally, with both of the previous points of reference (WHO and United Kingdom) not even the cases rejected by the court are interventions that would be recommended according to the economic value they are assigned.

Finally, a third point of reference for recommendations in healthcare systems is the United States. Here more than three quarters of cost-utility analyses use values between 50,000 and 100,000 dollars per quality adjusted life year (QALY) as a threshold (Cameron et al., 2018). The QALY is a summary outcome measure that quantifies the effectiveness of an intervention using the impact of quality life gained thanks to a treatment and life expectancy. For the United States, the monthly thresholds mentioned correspond to 4,167 and 8,333 dollars. By these thresholds, the Court's approved cases pass the exclusion criteria and with this recommendations they should be offered to these patients by the public insurer.

Considering the WHO rule is aimed at nascent public health care systems it is not surprising Costa Rica is making decisions above this standard threshold. For the United States recommendations it is also to be expected that all of the Court's cases should be approved. This is because the United States has a privately driven system. In contrast, what is more salient is that a wealthy developed nation, as the United Kingdom, with a well-established health care system, has thresholds below the Court's decisions.

7. Discussion and Conclusions

Resource scarcity and rationing is common to all healthcare systems. Particularly in public healthcare systems this inevitably causes a trade-off between individual and collective preferences. Individuals will consequently seek a way to bypass rationing with litigation as a main mechanism to do so. On one hand, this allows access that would otherwise not exist to health care services, but on the other, it reallocates resources from a plan that a collective had already agreed upon.

While insurers have a standard based on economic evaluations to decide on the rationing of services, the decision criteria used in litigation, which challenges these decisions, is not as straightforward. One of the limitations to describing this mechanism beyond anecdotal evidence has been access to data. Using this novel hand-collected dataset for the universe of Costa Rican litigation requesting drugs, it is possible to shed some light to understand more of this process.

First, results indicate that individual socioeconomic characteristics do not influence judges' ruling on whether a drug request is approved or not. This is relevant to look into the possibility of discrimination or thinking about social determinants of healthcare.

Second, constructing a measure of benefits based on best clinical practice guidelines show that higher benefit drugs have only a weakly positive effect on approval probabilities. As for costs, these do not appear to influence judges' decisions.

Lastly, marginal benefits are non-significant and marginal costs (as an approximation to cost-benefit ratios) have small to no effect. On one hand these findings support existing literature in economics and law, which suggests that although legal decisions may be presented in an economic context, judges seldom rely on economic concepts when making their rulings (Clarke and Kozinski, 2019). Furthermore, we should not expect the Court to follow threshold considerations as a standard the same way a PI does. Or if that were the case, it would draw into question the current thresholds set by the PI to make treatments available as they ration resources and how there are gaps in coverage for those meeting the criteria but not going to Court.

Access to health care is recognized as one of the most complex public policy issues around the world, and rationing is a salient concern. Even when discussed outside of the discipline of economics, the concepts used are from an economics framework (Liscow, 2014). Even so, the results do not show that economics is the main determinant for litigation which

is essentially focused on access to healthcare. Even if individually a person's preferences would not agree with rationing, their preference regarding government rationing is that it is done using economic evaluations (Cameron et al., 2018). In this specific scenario, Court decisions not being based on economics would theoretically fail to improve social well-being by this standard.

The analysis throughout this paper would require additional assumptions to make inferences about an optimal rationing mechanism. The paper presents and important step in understanding litigation as a safety valve for health care rationing and results are useful for setting up future economic models that can more precisely quantify its impact on individuals and society.

Another key finding of the analysis has been to see that, despite previous misconceptions or often the public's narrative, judges don't appear as partial as commonly seen in terms of "indiscriminately" approving or denying requests. At the same time, again contradicting what is frequently generally portrayed in these cases, the Court does not appear to be solely focused on individual patient benefits. Nevertheless, despite some positive results in terms of the safety valve functioning for the public health system, there is space to indicate the more 'technical' and 'recommended' criteria for decision making and rationing in health care is not significantly predominating in the rulings. This, together with the sponsorship effect found by testing judge panels, leaves room for both improvement in the policy as well as further research to study the decision making process for judges.

Considering the strain health care systems often find themselves in, the question of how to ration is both increasingly complex and urgent (Liscow, 2014; Chandra and Staiger, 2017). A mechanism such as litigation sheds light on the need for both flexibility and structure. Flexibility to account for individual heterogeneity in demand, and structure to ensure effectiveness in resource allocation.

We find that no pattern is evidenced for both prevalence and mortality. The lack of a pattern from the types of cancers involved in access to drugs litigation may grant some merit to the Costa Rican system's claim to be providing comprehensive and universal coverage. This supports the possible contribution of the Court as a complimentary mechanism for access to drugs with its possible ability to address individual heterogeneity in the population. This is an ability that institutions making population level rationing rules lack (Cameron et al., 2018).

Furthermore, it is relevant to see that caution (at least by taking prevalence of a disease into consideration) is not a key factor while judges highly value survival when making judgments about the merit of a request. This is seen in the fact that increasing survival increases the likelihood of approval. From the results and current economics and law literature (Clarke and Kozinski, 2019), there is no evidence that economic concepts such as effectiveness are used in judicial rulings, however the finding regarding mortality suggests that there could be a role for these concepts.

Such an inclusion could attempt to address concerns that a mechanism like litigation without clear rules will not use resources appropriately. Parallel to this, as high mortality diagnoses have higher cost benefit ratios it supports that the Court is focusing on any benefits more than being concerned with costs. This suggests that even if concerns on the scarcity of resources reallocated to these individuals may be exaggerated in public opinion, they cannot be dismissed without further evidence.

With the inevitable rationing of resources and the imperative need to design rules for this in the public provision of health, litigation has gained a key role as a tool for individuals excluded from a health service to bypass said rationing. Without an understanding of the factors involved in the decision making process of courts and the social costs of litigation, it is hard to evaluate the need of this type of safety valves. To evaluate this side of the possible implications of litigation, a first approach is to look into the trends of litigation as well as compare the functioning of a system with respect to key economic considerations, of which ICERs are a standard of.

Inequality and universalism are concepts at the center of policy design and even more so with publicly funded health care systems as the one in Costa Rica. This is part of what has led to one of the main concerns in the country, how approval of access to certain treatments by the court could lead to higher rates of litigation from more individuals. The idea is that this would represent a greater strain on the system in the future. Consequently there is a call for greater caution. Now, event study models have limitations but they also have an important role in policy analysis and help us asses the pattern of requests (Freyaldenhoven et al., 2019; Dobkin et al., 2018). Using this to evaluate data on Costa Rica's litigation for access to cancer drugs did not back up these concerns completely.

Currently in Costa Rica, the Public Insurer's only policy associated to litigation for drug access is updating drug coverage lists. There were 82% of cases requesting an uncovered drug. In virtually every case, the public insurer's defense stated that the drug was evaluated, found lacking in value and therefore not covered. However, predicting drug request trends relative to when a drug gains coverage showed no evidence of a clear relationship there. This finding suggests that concerns of potentially higher volumes of litigation with more request approvals may not have as much ground based on the evidence so far. However, it is also possible that part of the lack of evidence

of an impact here is precisely because of cautionary behavior from judges towards approving more of the requests presented, even if this does not follow prevalence as their criterion. More importantly, it would be the case that either the public insurer allows the Court to continue to serve as safety valve or it would need to reform its policies and find an alternative outlet as the current setup does not appear to attempt to affect litigation for drug access.

These facts and conclusions drawn contribute to understanding how litigation serves as a safety valve for health care rationing, and the many factors that future economic models must consider when evaluating the impact this phenomenon has on individuals and society. Empirical evidence for this matter is limited to the results found from this data.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Data availability

Data will be made available on request.

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